UNITED STATES DISTRICT COURT
DISTRICT OF VERMONT

BLUE CROSS AND BLUE SHIELD OF VERMONT and THE VERMONT HEALTH PLAN,

Plaintiffs,

v.

TEVA PHARMACEUTICAL INDUSTRIES, LTD., TEVA PHARMACEUTICALS USA, INC., TEVA SALES AND MARKETING, INC., and TEVA NEUROSCIENCE, INC.,

Defendants.

COMPLAINT— CLASS ACTION

JURY DEMAND

CASE NO. 5:22-cv-159

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Plaintiffs, individually and on behalf of all others similarly situated, bring this Class Action Complaint against Defendants Teva Pharmaceutical Industries, Ltd., Teva Pharmaceuticals USA, Inc., Teva Neuroscience, Inc., and Teva Sales & Marketing, Inc. (collectively, "Teva" or "Defendants") and alleges the following based upon personal knowledge, information and belief, and investigation of counsel:

I. INTRODUCTION

1. This case concerns a pharmaceutical company's decade-long anticompetitive scheme to thwart competition to induce health insurers and health plans in the United States to pay billions for its excessively priced multiple sclerosis drug.

2. Multiple sclerosis ("MS") is a debilitating disease that causes the body's immune system to attack the central nervous system. Patients with MS experience a range of symptoms, including fatigue, weakness, vision problems, and cognitive deficits. The most common form of MS, relapsing-remitting multiple sclerosis ("RRMS"), is characterized by clearly defined attacks of new or increasing symptoms followed by periods of remission, during which symptoms partially or completely subside.

3. Glatiramer acetate is an injectable drug that has been approved by the U.S. Food and Drug Administration ("FDA") to treat RRMS. Glatiramer acetate simulates the protective protein that surrounds nerve fibers and thus blocks or otherwise interrupts the immune system attacks associated with RRMS. While glatiramer acetate helps alleviate symptoms of MS, there is no known cure for MS. As a result, many patients remain on glatiramer acetate for many years.

4. Although Teva did not develop glatiramer acetate, it has licensed the rights to the drug since 1987 and claims to hold all patents on the drug. In 1997, following approval from the FDA, Teva began selling glatiramer acetate under the brand name Copaxone.

5. When Teva first began selling Copaxone in 1997, it set the price for a *monthly course of treatment at $769.15*. That price remained until 2000, after which Teva began annual price increases that resulted in a price of approximately $1000 per month by 2003. But that was

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only the beginning of Teva's increasingly aggressive pricing strategy, which saw Teva increase the price of Copaxone *twenty-seven times*, until it reached a monthly cost of *$5,832* by 2017.

6. A September 2020 report from the United States House Committee on Oversight and Reform concluded that Teva's costs did not come anywhere close to justifying these price increases.[1] Rather, Teva reaped excessive profits from Copaxone. Between 2002 and 2019, Teva's net revenue from Copaxone sales in the United States alone exceeded $34 billion.

7. Incredibly, Teva was able to increase prices—and obtain these massive profits—without losing sales to lower-cost generic versions of glatiramer acetate. Teva accomplished this feat by employing an anticompetitive scheme that caused health care payors, like Plaintiffs, in the United States to substantially overpay for glatiramer acetate.

8. Teva began by abusing patent litigation and the FDA's citizen petition process, to artificially prolong Copaxone's patent exclusivity and block lower-cost generics from entering the market.

9. But even after generics entered the market, Teva unlawfully suppressed competition. Put simply, Teva preyed upon the fundamental disconnect between the entities that pay for prescription medications (employers and insurers who pay claims incurred by health plan members) and the individuals and entities that determine which products are ultimately purchased (doctors, pharmacists, benefit managers, and health plan members). Teva used myriad anticompetitive, unfair, and deceptive practices to manipulate the individuals and entities that selected products, knowing these individuals were mostly (if not entirely) insulated from the cost of Copaxone. It manipulated the prescribing decisions of doctors, the product selection decisions of pharmacists, the drug prioritization and formulary decisions of pharmacy benefit managers, and the purchasing decisions of health plan members. By causing these entities to select or dispense Copaxone instead of lower-cost generics, Teva suppressed generic competition and

[1] Staff of H.R. Comm. on Oversight and Reform, 116th Cong., Drug Pricing Investigation Teva-Copaxone (Sept., 2020), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Teva%20Staff%20Report%2009-30-2020.pdf ("House Report").

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caused employers and insurers to pay for—and continue paying for—Copaxone despite its ever-increasing price.

10. The scheme consisted of multiple components. ***First***, Teva manipulated the purchasing decisions of health plan members by circumventing the cost-sharing obligations that health plans used to help make members sensitive to price. Most health plans require members to pay co-insurance or copayments, which represent a portion of the purchase price of prescription drugs and other medical care. These payments are designed to make members at least partially internalize the cost of prescriptions so they will prefer more affordable treatment options and not cause plan payors to incur excessive costs. Given these cost-sharing arrangements, Teva knew plan members would prefer more affordable generic versions of glatiramer acetate. Rather than making the price of Copaxone more affordable, Teva provided health plan members with "coupons" that relieved them of some or all of their cost-sharing obligations if they purchased Copaxone. This meant that for health plan members, Copaxone would be less expensive than generics. Unfortunately, for health plan payors—the entities that pay the bulk of the cost for all prescriptions—Copaxone remained excessively priced. In this way, Teva avoided price competition by insulating decision-makers from the true cost of Copaxone. Teva thus induced health plan payors to continue paying for Copaxone instead of lower-cost generics.

11. As detailed below, for Teva to be able to maintain high prices without losing sales, it would have to extend this form of "copay assistance" to the vast majority of health plan members in the United States, including Medicare recipients and members of private health plans. To pull off such an elaborate scheme, Teva conspired with specialty pharmacies, non-profit foundations, and other entities and engaged in a variety of illegal, anticompetitive, unfair, and deceptive acts.

12. ***Second***, Teva manipulated pharmacy-level dispensing by circumventing drug substitution laws through an anticompetitive product-hop scheme. Drug substitution laws allow or require pharmacists to substitute generic versions for a prescribed brand-name drug. These

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laws play an important role in lowering health plan costs, as they typically cause health plans to pay for lower-costs generics instead of higher-cost brand versions of the same drug. But these laws allow substitution only if generics are "therapeutically equivalent" to the brand drug, including if they are of the same form, dosage, and strength. When Copaxone was nearing the end of its patent exclusivity, Teva launched a new 40mg, three-times-a-week formulation to avoid drug substitution laws. Teva, in collusion with pharmacy benefit managers, then resorted to anticompetitive, unfair, and deceptive tactics to coerce and otherwise induce patients and doctors to switch to the new dosage, over which Teva improperly claimed and for some time received extended patent exclusivity. As a result, even when generic forms of 20mg glatiramer acetate were available for sale in the United States, the majority of health plan members were being prescribed 40mg Copaxone. And, because 40mg Copaxone is a different dosage than 20mg glatiramer acetate, pharmacists could not substitute the more affordable generic.

13. ***Third***, when 40mg generic glatiramer acetate entered the market after Teva's patent on the new dosage was invalidated, Teva implemented a multi-pronged offensive to ensure that health plan members continued to receive—and health plan payors continued to pay for—its excessively-priced Copaxone products. It resorted to material misrepresentations and deployed an extensive campaign to pressure doctors to write prescriptions with a "dispense as written" notation, which precluded pharmacists from substituting with available generics. It conspired with pharmacy benefit managers to make Copaxone the favored form of glatiramer acetate under the PBMs' drug "formularies," the prioritized lists of drugs made available to health plan members. It conspired with specialty pharmacies, which agreed to fill prescriptions with Copaxone even if the prescriptions were written for a lower-cost generic. And it engaged in an elaborate outreach campaign to health plan members—who, because of Teva's copay assistance program, were not sensitive to price—to induce them to request their doctors keep writing prescriptions for brand-name Copaxone with the "dispense as written" notation.

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14. The end result was that generic forms of glatiramer acetate were unable to meaningfully compete with Copaxone and Teva was able to maintain and exploit its monopoly in the market for glatiramer acetate, including by charging supercompetitive prices. This caused health plan payors to unnecessarily expend billions of dollars on Copaxone. But for the anticompetitive conduct of Teva and its co-conspirators, health plan payors would have spent far less on glatiramer acetate, as they would have paid for either more affordably priced Copaxone or lower-cost generics.

15. Plaintiff Blue Cross and Blue Shield of Vermont (BCBSVT) is a nonprofit organization that provides health insurance for individuals, families, and businesses, meaning that BCBSVT pays for prescription medications for covered individuals. When prescription drugs are overpriced, BCBSVT pays the inflated prices. BCBSVT and its subsidiary The Vermont Health Plan have paid more for Copaxone than they would have spent on glatiramer acetate but for Teva's anticompetitive, deceptive, and manipulative conduct.

16. Plaintiffs bring this action to hold Teva accountable for its anticompetitive, unfair, manipulative, and deceptive actions to obtain excessive profits on a critical treatment for a debilitating disease. This conduct violates state antitrust and consumer protection laws and has unjustly enriched Teva. Plaintiffs seek to recover damages and overpayments from at least 2006 through the present, and to obtain declaratory and injunctive relief to cease this harmful conduct. Plaintiffs also seek treble damages, attorneys' fees, costs, and punitive damages.

II. JURISDICTION AND VENUE

17. This Court has subject-matter jurisdiction over Plaintiffs' federal claims pursuant to 28 U.S.C. § 1331 (federal question), § 2 of the Sherman Act, and §§ 4 and 16 of the Clayton Act.

18. This Court has supplemental jurisdiction over Plaintiffs' pendent state law claims pursuant to 28 U.S.C. §1367.

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19. This Court has jurisdiction over this action pursuant to 28 U.S.C. §1332(a) because the amount in controversy exceeds $75,000 (exclusive of interest and costs) and no Plaintiff shares a state of citizenship with any Defendant. This Court also has jurisdiction over this action pursuant to 28 U.S.C. §1332(d) because this is a class action in which the aggregate amount in controversy exceeds $5,000,000 (exclusive of interest and costs), the number of the members of the Class exceeds 100, and at least one member of the putative Class is a citizen of a state different from that of one of the Defendants.

20. The Court has personal jurisdiction over Defendants because they conduct business in Vermont, have purposefully directed their actions toward Vermont, and have sufficient minimum contacts with Vermont. Defendants intentionally avail themselves of the markets in this State through the promotion, marketing, and sale of the products at issue in this lawsuit. Moreover, Plaintiffs' claims arise out of, or relate to, Teva's contacts with the State of Vermont.

21. Alternatively, the Court has personal jurisdiction over Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") because Teva Ltd. is an alter ego of its United States subsidiaries, Defendants Teva Pharmaceuticals USA, Inc., Teva Neuroscience, Inc., and Teva Sales & Marketing, Inc, over which the Court has personal jurisdiction for the reasons stated in the preceding paragraph.

22. This Court's exercise of personal jurisdiction over Teva Ltd. comports with due process because Teva Ltd. conducts business in the United States, has purposefully directed its actions toward the United States, and has sufficient minimum contacts with the United States.

A. Teva Ltd. intentionally avails itself of U.S. markets. Teva Ltd. describes itself as "the leading generic pharmaceutical company in the United States."[2] It

[2] Teva Ltd., Form 10-K Annual Report for the fiscal year ended December 31, 2019, at 3, https://sec.report/Document/0001193125-20-044221/ ; *see also id* at 5 ("We are the leading generic pharmaceutical company in the United States…") ("Teva Ltd. 2019 10-K").

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acknowledges that it is subject to "significant" regulation by the United States, including inspection of its facilities by FDA, among other significant regulatory burdens.[3]

B. Teva Ltd. intentionally avails itself of U.S. markets significantly through the promotion, marketing, and sale of the products at issue in this lawsuit.[4] Teva Ltd. has described Copaxone as "our leading medicine,"[5] and as "one of the leading MS therapies in the United States."[6]

C. Teva Ltd. further intentionally and repeatedly avails itself of the federal court system as a plaintiff in patent-related litigation, including dozens of cases addressing the very products at issued in this lawsuit. Teva Ltd. has sued FDA for its refusal to treat Copaxone as a biologic,[7] and has sued FDA over its denial of a citizen petition relating to Copaxone generic products.[8] Teva Ltd. has been a plaintiff in

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[3] *Id.* at 19-20.

[4] *See, e g , Adapt Pharma Operations Limited v Teva Pharmaceuticals USA, Inc.*, 16-cv-07721, ECF No. 9 ¶ 8 (D.N.J. 2017) (Teva Ltd. and Teva USA "manufactur[e] and distribut[e] generic drugs for sale and use throughout the United States, including in" the District of New Jersey); *Zydus Worldwide DMCC v Teva Pharmaceuticals Industries Inc.*, Docket No. 654824/2019 ("*Zydus*"), NYSCEF No. 1 at ¶ 7(Teva Ltd. "directly and through its subsidiaries is engaged in the business of manufacturing and selling pharmaceutical products and API used to make pharmaceutical products.")

[5] Teva Ltd., Form 10-K Annual Report Form 10-K for the fiscal year ended December 31, 2018 at 1 ("Teva Ltd. 2018 10-K").

[6] *Id.* at 6.

[7] Teva Pharmaceuticals USA, Inc. & Teva Ltd. v. United States Food and Drug Admin., et al., Case No. 1:20-cv-00808 (D.D.C.) filed March 24, 2020.

[8] Teva Ltd., et al. v. Sibelius et al., Case No. 1:14-cv-00786 (D.D.C.) filed May 9, 2014.

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numerous suits against generic manufacturers alleging infringement of the patents for both Copaxone 40mg[9] and 20mg,[10] among other litigation filed in U.S. courts.[11]

D. Teva Ltd. directs activities, submissions, and dealings with the U.S. FDA and FTC.

E. Plaintiffs' claims arise out of, or relate to, Teva's contacts with the United States.

23. Venue is proper in the District of Vermont pursuant to 28 U.S.C. § 1391 (b)(2) and (3) because a substantial part of the events or omissions giving rise to the claims at issue in this Complaint arose in this District and Defendants are subject to the Court's personal jurisdiction with respect to this action.

III. PARTIES

A. Plaintiffs

24. Plaintiff Blue Cross and Blue Shield of Vermont ("BCBSVT") is a nonprofit hospital service corporation and a nonprofit medical service corporation organized under the laws of Vermont, with its principal place of business in Berlin, Vermont. *See* Vt. Stat. Ann. tit. 8, §§ 4511–23 (defining nonprofit hospital service corporations); *id.* §§ 4581–95 (defining nonprofit medical service corporations). BCBSVT offers health insurance, including

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[9] *See, e g.*, Teva Pharmaceuticals USA, Inc. & Teva Ltd. v. Amneal Pharma, et al., Case No. 2:17-cv-00416 (E.D.N.Y); Teva Pharmaceuticals USA, Inc. & Teva Ltd. v. Dr. Reddy's Labs., Ltd., et al., Case No. 3:17-cv-00517 (D.N.J.); Teva Pharmaceuticals USA, Inc. & Teva Ltd. v. Sandoz Pharma, et al., Case No. 3:17-cv-00275 (D.N.J.); Teva Pharmaceuticals USA, Inc. & Teva Ltd. v. Synthon Pharmaceuticals, Inc. et al, Case No. 1:17-cv-00345 (S.D.N.Y.); Teva Pharmaceuticals USA, Inc. & Teva Ltd. v. Mylan Pharma., Inc., et al., Case No. 1:17-cv-00007 (N.D. W. Va.); Teva Pharmaceuticals USA, Inc. & Teva Ltd. v. Biocon Ltd. et al, Case No. 16-cv-00278 (D. Del.); Teva Ltd., et al v. Amneal Pharma, et al., Case No. 15-cv-00124 (D. Del.);Teva Ltd., et al v. Synthon Pharmaceuticals, Inc. et al, Case No. 1:14-cv-00975 (M.D.N.C.); Teva Ltd., et al. v. Mylan Pharma., Inc., et al., Case No. 1:14-cv-00167 (N.D. W. Va.).

[10] *See, e g.*, Teva Ltd., et al v. Synthon Pharmaceuticals, Inc. et al, Case No. 2:15-cv-00472 (D.N.J.); Teva Ltd., et al v. Dr. Reddy's Labs., Ltd., et al., Case No. 2:15-cv-00471 (D.N.J.); Teva Ltd., et al v. Synthon Pharmaceuticals, Inc. et al, Case No. 5:12-cv-00179 (E.D.N.C.); Teva Ltd., et al v. Synthon Pharmaceuticals, Inc. et al, Case No. 1:12-cv-02556 (S.D.N.Y.); Teva Ltd., et al v. Sandoz Pharma, et al., Case No. 1:09-cv-10112 (S.D.N.Y.); Teva Pharmaceuticals USA, Inc. et al v. Mylan Pharmaceuticals, Inc. et al, 1:09-cv-00152 (N.D. WV).

[11] *See, e g.*, *Teva Pharmaceutical Industries Ltd. vs. Dr Reddy's Laboratories*, Index No. 656499/2021, NY Sup. Ct., NY County, Comm. Division; *Adapt Pharma Operations Limited v Teva Pharmaceuticals USA, Inc.*, 16-cv-07721 (D.N.J. 2017).

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prescription drug benefits, for individuals, families, and businesses. BCBSVT purchases, pays for, and/or provides reimbursement for some or all of the purchase price of prescription drugs dispensed to members of its health plans. BCBSVT purchased, paid for, and/or provided reimbursement for some or all of the purchase price of Copaxone prescriptions dispensed to members of its plans. BCBSVT continues to purchase, pay for, and/or provide reimbursement for some or all of the purchase price for Copaxone prescriptions dispensed to members of its plans.

25. Plaintiff The Vermont Health Plan ("TVHP") is a licensed health maintenance organization and a for-profit subsidiary of BCBSVT, with its principal place of business in Berlin, Vermont. TVHP provides large group coverage to employers in Vermont. See Vt. Stat. Ann. tit. 8, §§ 5101-5115 (governing health maintenance organizations). TVHP offers health insurance, including prescription drug benefits, for individuals, families, and businesses. TVHP purchases, pays for, and/or provides reimbursement for some or all of the purchase price of prescription drugs dispensed to members of its insured health plans. TVHP purchased, paid for, and/or provided reimbursement for some or all of the purchase price of Copaxone prescriptions dispensed to members of its insured plans. TVHP continues to purchase, pay for, and/or provide reimbursement for some or all of the purchase price for Copaxone prescriptions dispensed to members of its insured plans.

26. Plaintiffs purchased, paid for, and/or provided reimbursement for some or all of the purchase price of Copaxone prescriptions dispensed in the following states: Alabama, Arizona, California, Delaware, Florida, Georgia, Indiana, Kansas, Massachusetts, Maine, Michigan, New Hampshire, New York, Pennsylvania, Tennessee, and Vermont.

B. Defendants

27. Defendant Teva Pharmaceutical Industries, Ltd. ("Teva Ltd.") is an Israeli corporation with its principal place of business in Petah Tikva, Israel. Teva Ltd.'s shares are publicly traded in the United States.

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28. Defendant Teva Pharmaceuticals USA, Inc. ("Teva USA"), is a Delaware corporation with its principal place of business in Parsippany, New Jersey. Teva USA is a wholly owned subsidiary of Teva Ltd.

29. Defendant Teva Neuroscience, Inc. ("Teva Neuroscience"), is a Delaware corporation with its principal place of business in Overland Park, Kansas. It is a wholly owned subsidiary of Teva USA.

30. Defendant Teva Sales & Marketing ("Teva S&M"), is a Delaware corporation with a principal place of business at 11100 Nall Ave., Overland Park, Kansas, 66211. Teva S&M is a subsidiary of Teva Ltd.

31. For purposes of clarity, Plaintiff herein collectively refers to Teva Ltd., Teva USA, Teva S&M, and Teva Neuroscience as "Teva." Teva manufacturers, markets, and sells Copaxone throughout the United States.

C. Teva Ltd. Is the Alter Ego of Teva USA, Teva Neuroscience, and Teva S&M

32. Teva USA and Teva S&M are wholly owned subsidiaries of Teva Ltd., and Teva Ltd. is the only publicly traded company that owns 10% or more of the stock of Teva USA. Teva Neuroscience is a wholly owned subsidiary of Teva USA.

33. Teva Ltd. repeatedly describes itself as a single, "global" entity. Teva Ltd.'s Code of Conduct addresses its "global workforce" and declares that it is "[t]housands of people, across many countries, speaking a multitude of languages, with one mission," which is "to be a global leader in generics and biopharmaceuticals."[12] Teva Ltd.'s Statement of Corporate Governance Principles emphasizes the "complexity of Teva's businesses and its extensive global activity."[13] Teva Ltd.'s Code of Conduct further states that "[w]e understand that in order to achieve our common goals we need to engage our employees around the world, across different divisions and

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[12] Teva Ltd., *Teva's Code of Conduct*, (Dec. 9, 2020), https://www.tevapharm.com/globalassets/tevapharm-vision-files/tevas-code-of-conduct---v3---12.09.20---english.pdf ("Teva's Code of Conduct").

[13] Teva Ltd., *Statement of Corporate Governance Principles*, at 1 (last updated Nov. 4, 2020) https://www.tevapharm.com/globalassets/tevapharm-vision-files/statement-of-corporate-governance-principles---november-2020.pdf ("Statement of Corporate governance Principles").

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in different functional areas."[14] Teva Ltd. boasts that "[o]ur work impacts economies and healthcare systems around the world."[15]

34. According to facts unsealed by the district court's order in *City and County of San Francisco v. Purdue Pharma L.P.* ("SF Order"), 491 F. Supp. 3d 610, at 636 (N.D. Cal. 2020), Teva Ltd. depicts itself as "One global brand, One story, One Teva," and Teva Ltd.'s indirect subsidiaries "report directly to Teva Ltd." *Id.* "According to a 2018 'Segment Memorandum,' Teva Ltd.'s CEO is 'ultimately responsible' for allocating all of Teva's resources." *Id.* "Around the same time, Teva Ltd. implemented 'a new organizational structure' to help integrate Teva 'into one commercial organization,' thereby blurring the layers of separation between Teva Ltd. and its subsidiaries." *Id.*

35. The SF Order also found that "[t]he head of Teva Ltd.'s Global Research and Development division controls Teva's product formulation, design, and commercial execution." *Id.* Indeed, Teva Ltd. claims that it has a "fully integrated R&D function" that has accomplished 100 "pending first-to-file ANDAs in the U.S." and 270 "product registrations pending FDA approval."[16] The SF Order also found that "Teva Ltd. implemented guidelines that enabled it to nominate, select, and approve the Executive Committee and Sub-committee members for itself and its U.S. subsidiaries, resulting in substantial control over the subsidiaries' marketing, administration, manufacturing, research and development, purchase of supplies, finance, and 'other significant supporting operations conducted in "shared and commingled assets."'" *Id.* at 636-637.

36. Teva Ltd. and Teva USA also share employees and corporate officers, with Teva Ltd. controlling the activities of Teva USA. According to facts unsealed by the district court's

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[14] Teva's Code of Conduct at 22, https://www.tevapharm.com/globalassets/tevapharm-vision-files/tevas-code-of-conduct---v3---12.09.20---english.pdf.

[15] *Economic Impact Report*, Teva Ltd., https://www.tevapharm.com/our-impact/economic-impact-report (last visited Sept. 27, 2021)

[16] Teva Ltd., *Facts and Figures*, (May 2020) https://www.tevapharm.com/globalassets/scs-files---global/teva-infographic-files/teva_infographic_english_may2020.pdf

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order in *In re Natl. Prescription Opiate Litig.*, 1:17-MD-2804, 2019 WL 3553892, at *4 (N.D. Ohio Aug. 5, 2019), "Teva Ltd. controls the operations of its subsidiaries through an integrated management team via Global Divisions" and "Debra Barrett, as [a] Teva USA employee, coordinated and directed advocacy, lobbying, and policy development across the entire Teva group of companies." *Id.* "Any proposed corporate contribution or political activity" conducted by Teva Ltd. or its subsidiaries is required to "be reviewed and approved by Teva [Ltd.]'s Global Government Affairs and Public Policy Department."[17] The Compliance Committee of Teva Ltd.'s Board of Directors has the responsibility to "review and oversee the Company's global public policy positions and government affairs activities."[18] "Teva's Tax function is organized on a global basis to ensure consistent tax policies, strategies and processes across regions and locations for all tax aspects at all levels."[19]

37. Teva's global "[m]arketing and promotional practices are under the responsibility of [Teva Ltd.'s] Executive Vice President for Global Marketing & Portfolio."[20] Moreover, "Teva [Ltd.]'s global internal audit department periodically audits marketing and promotional material compliance."[21] And with respect to marketing and promotional practices, Teva Ltd. describes how it "maintains a global and comprehensive compliance and ethics program that meets or exceeds all of the elements proposed by the U.S. Department of Justice, Office of the Inspector General," including "a systematic annual risk assessment supported by corrective actions as required across different Teva divisions and in different markets."[22]

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[17] Teva's Code of Conduct at 17, https://www.tevapharm.com/globalassets/tevapharm-vision-files/tevas-code-of-conduct---v3---12.09.20---english.pdf.

[18] Teva Ltd., *Compliance Committee Charter*, at 2 (Dec. 3, 2020), https://www.tevapharm.com/globalassets/tevapharm-vision-files/compliance-committee-charter-december3-2020-new-format.pdf.

[19] Teva Ltd., *Teva's Group Tax Policy*, at 4, https://www.tevapharm.com/globalassets/tevapharm-vision-files/teva-global-tax-policy-26072020.pdf.

[20] Teva Ltd., *Teva's Position on Marketing and Promotional Practices*, at 3, https://www.tevapharm.com/globalassets/tevapharm-vision-files/tevas-marketing-position-_2020.pdf.

[21] *Id.*

[22] *Id.*

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38. Teva also adopted an enterprise-wide customer relations management ("CRM") system in 2014.[23] According to a press release announcing the change,

> In an enterprise-wide drive to harmonize its commercial operations, Teva Pharmaceuticals is standardising on Veeva Systems' multichannel CRM system. Teva is replacing its legacy systems across 45 markets worldwide with Veeva's cloud-based solution to streamline operations and enable global collaboration across both generic and branded drug commercial teams. Veeva CRM, already deployed across U.S. field teams, is now being rolled out in Europe with plans to phase in other Teva regions over the next several months.[24]

In discussing the change, Teva Ltd.'s Chief Information Officer, Guy Hadari, stated that "Veeva CRM provides us the foundation for long-term success by allowing us to capture valuable customer insights about channel preferences and content needs globally."[25] He further explained that Veeva "increases efficiency by connecting commercial teams and regions in the cloud that had been highly fragmented."[26]

39. Teva Ltd. utilizes global policies that govern its operations throughout the world, including within the United States. Teva Ltd. has a global "Policy on the Prevention of Corruption," which is overseen by a Global Chief Compliance & Ethics Officer.[27] Teva Ltd. also has a "Global Customs and Trade Controls Policy" and a "Global Data Privacy Policy."[28] Teva Ltd. explains the importance of its global trade controls by noting that "Teva does business all over the world, and the laws of one country or jurisdiction may apply to transactions or activities

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[23] *Teva Harmonizes All Commercial Teams Worldwide with Veeva Systems' Cloud-based CRM Solution*, Businesswire (May 28, 2014, 7:03 AM), https://www.businesswire.com/news/home/20140528005686/en/Teva-Harmonizes-All-Commercial-Teams-Worldwide-with-Veeva-Systems'-Cloud-based-CRM-Solution.

[24] *Id.*

[25] Veeva Systems, *Teva Pharmaceuticals Unifies Global Commercial Strategy with Veeva CRM*, at 2, https://www.veeva.com/wp-content/uploads/2016/03/Teva-UK-Veeva-CRM-Case-Study-NA.pdf.

[26] *Id.*

[27] Teva Ltd., *Prevention of Corruption*, https://www.tevapharm.com/globalassets/tevapharm-vision-files/prevention-of-corruption---v2---04.15.18---english-ethics.pdf.

[28] Teva's Code of Conduct at 13, 26, https://www.tevapharm.com/globalassets/tevapharm-vision-files/tevas-code-of-conduct---v3---12.09.20---english.pdf.

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that occur elsewhere."[29] Additionally, Teva Ltd.'s "Board has adopted a global 'whistleblower' policy, which provides employees and others with an anonymous means of communicating with [Teva Ltd.'s] Audit Committee."[30]

40. On information and belief, and as detailed below, Teva Ltd. directed and approved the conduct of Teva's U.S. subsidiaries, Teva USA, Teva Neuroscience, and Teva S&M, including the very conduct at issue in this case. Teva Ltd. has represented in court filings that it is "substantially identical" to one of its wholly owned U.S. subsidiaries,[31] and that it participates in the sale and/or management of facilities in the United States[32] and business lines in the United States.[33]

41. With respect to the conduct at issue in this case specifically, Teva Ltd.'s most senior executives were involved in key decision-making processes regarding the marketing and sale of Copaxone within the United States, including the anticompetitive, unfair, and deceptive conduct Teva utilized to induce payors to continue purchasing Copaxone at high prices instead of purchasing lower-cost generics. Among other things, Teva Ltd. executives were required to approve large donations from Teva to third-party foundations and were critically involved in Teva's strategic process to "develop a low frequency formulation of [glatiramer acetate]" to "ensure 'the competitiveness of Copaxone in the future . . . .'" House Report at 16, 27.

42. Teva Ltd. derives substantial revenue from Copaxone sales in the United States, including from Vermont. Teva's SEC filings reflect that Copaxone is critical to Teva's financial

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[29] *Id.* at 18.

[30] Statement of Corporate governance Principles at 4, https://www.tevapharm.com/globalassets/tevapharm-vision-files/statement-of-corporate-governance-principles---november-2020.pdf.

[31] *Zydus Worldwide DMCC v. Teva Pharmaceuticals Industries Inc.*, Docket No. 654824/2019 ("*Zydus*"), NYSCEF No. 15 at 14-16.

[32] *Teva Pharmaceutical Industries Ltd. vs. Dr. Reddy's Laboratories*, Index No. 656499/2021, NY Sup. Ct., NY County, Comm. Division, NYSCEF Nos. 29 (at ¶¶ 3, 4, 38, 39, 44, 46), 33 (at ¶ 63), 38.

[33] *Zydus Worldwide DMCC v. Teva Pharmaceuticals Industries Inc.*, Docket No. 654824/2019 ("*Zydus*"), NYSCEF No. 1 at ¶¶ 10, 15.

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results,[34] and Teva has described Copaxone as "our leading medicine."[35] Teva's Copaxone revenue (North American segment) was $884 million dollars in 2020;[36] $1.017 billion in 2019;[37] $1.759 billion in 2018;[38] $3.116 billion in 2017;[39] and $3.543 billion in 2016.[40] According to the House Committee on Oversight and Reform, between 2012 and 2017, "Copaxone's net U.S. revenue made up 15% of Teva's net worldwide revenue for all products." House Report 3-4.

IV. FACTUAL BACKGROUND

A. Multiple Sclerosis

43. MS is an immune-mediated disease that causes the body's immune system to attack the central nervous system (the brain, spinal cord, and optic nerves). It is estimated that more than 900,000 people in the United States live with MS.

44. The most common form of MS is relapsing-remitting multiple sclerosis , with approximately 85 percent of all MS patients being initially diagnosed with RRMS. Patients suffering from RRMS experience clearly defined attacks of new or increasing neurologic symptoms, which are known as relapses or exacerbations. These attacks eventually subside and are followed by remissions, during which some or all symptoms disappear (though other symptoms may continue or become permanent).

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[34] Teva Ltd., Form 10-K Annual Report for the fiscal year ended December 31, 2020 ("Teva Ltd. 2020 10-K") at 29, https://s24.q4cdn.com/720828402/files/doc_financials/2020/q4/FY2020_10K_Feb.10.2021.pdf ("Our financial results depend upon our ability to develop and commercialize additional generic, specialty and biosimilar products in a timely manner, particularly in light of the increasing generic competition to COPAXONE…"); *see also id.* at 53 ("Our revenues in 2020 were $16,659 million, a decrease of 1% in both U.S. dollar and local currency terms, compared to 2019, mainly due to a decline in revenues from certain oncology products, COPAXONE and certain respiratory products…."); *id.* at 76 (reporting that Copaxone revenues will have "significant effect" on 2021 financial results); Teva 2019 10-K at 33 (reporting that its rating were downgraded following federal court invalidating Copaxone 40mg/ml patents); *id.* at 56 (attributing decrease in 2019 revenues, *inter alia*, "mainly due to generic competition to COPAXONE"); Teva 2018 10-K at 33 (describing ratings downgrade following unfavorable Copaxone patent decision).

[35] Teva Ltd. 2018 10-K at 1.

[36] Teva Ltd. 2020 10-K at 56.

[37] *Id.*

[38] Teva 2019 10-K at 59.

[39] *Id.*

[40] Teva 2018 10-K at 58.

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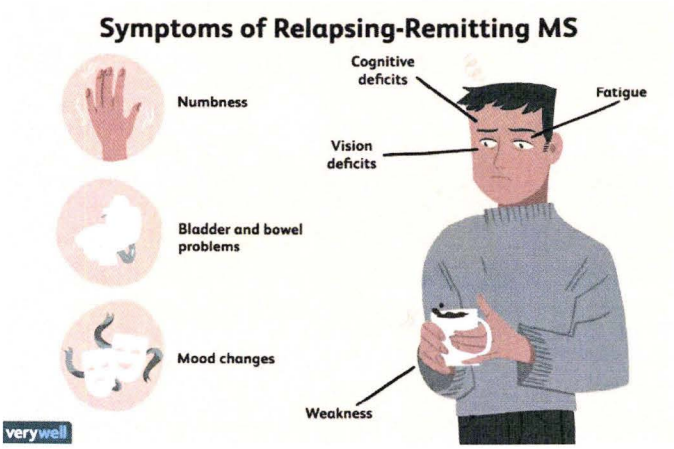
45. Relapses are caused by inflammatory attacks on myelin, which is a protein that covers and protects the nerve fibers in the central nervous system. These inflammatory attacks occur when certain of the body's immune cells, specifically T-cells, begin to attack myelin, as well as the nerve fibers themselves, in small, localized areas. When myelin or nerve fibers are damaged, messages within the central nervous system become disrupted, causing a variety of symptoms. The particular symptoms of a relapse depend on which areas of the central nervous system are attacked by these T-cells.

46. During relapses, symptoms may include fatigue, numbness, vision deficits, cognitive deficits (problems with learning, memory, or information processing), weakness, spasticity or stiffness, and bowel and bladder problems.



47. The cause of MS is unknown, but it is believed that environmental and genetic factors increase the risk of developing the disease.

48. MS is more prevalent in areas farther from the equator. Some researchers believe this is related to vitamin D: people living closer to the equator are exposed to more sunlight, exposure to sunlight is known to cause the skin to produce vitamin D, and evidence indicates that low vitamin D levels increase the risk of developing MS.

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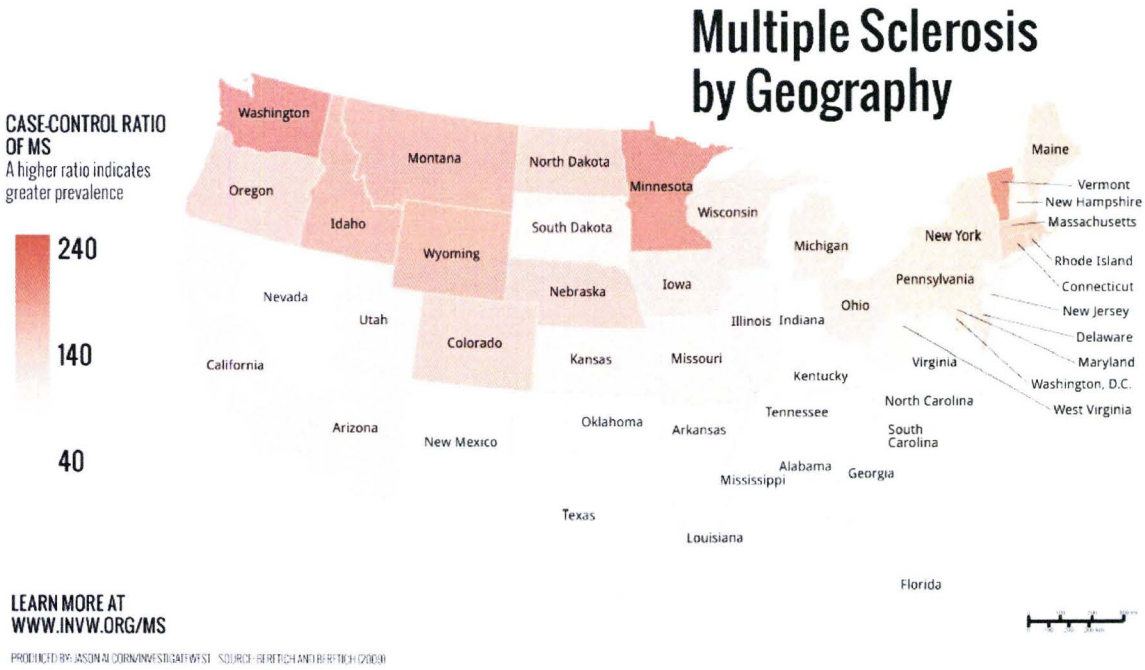
49. MS is particularly prevalent in northern states, including Vermont.



50. While MS afflicts nearly one million American adults, the rate of prevalence in Vermont is approximately twice the national average.

B. Copaxone

51. Copaxone is an injectable drug approved by the FDA to treat relapsing forms of MS, including RRMS. The active ingredient in Copaxone is glatiramer acetate, a chemically synthesized protein that simulates myelin. While glatiramer acetate does not cure MS, it is a disease-modifying therapy ("DMT") that helps reduce relapses by blocking T-cells or otherwise interrupting the immune system attack.

52. Although there are other DMTs approved by the FDA to treat relapsing forms of MS, these various DMTs use different mechanisms of action and routes of administration and are thus not therapeutically interchangeable. Since 2008, glatiramer acetate has been the DMT that is most commonly prescribed to treat relapsing forms of MS.

53. Teva Ltd. licensed the rights to Copaxone from the Weizmann Institute of Science in 1987 and claims to be the owner and/or exclusive licensee of glatiramer acetate patents.

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54. Teva USA is the exclusive U.S. licensee of glatiramer acetate patents.

55. The Food and Drug Administration approved Copaxone for treatment of RRMS in 1996.

56. Teva began selling Copaxone in March 1997.

57. Copaxone is Teva's leading brand name pharmaceutical product. "In 2015, Copaxone® revenues … amounted to $3.2 billion in the U.S. (approximately 29% of Teva's total 2015 U.S. revenues)."[41] Copaxone accounted for nearly one-fifth of Teva's North America net revenue between 2017 and 2019. House Report Executive Summary ("House Exec. Summ.") at i.

C. Teva Drastically Increased the Price of Copaxone

58. Teva has raised the price of Copaxone in the United States *27 times* since first releasing the drug in 1997. Teva increased the price of a yearly course of Copaxone from $10,000 in 1997 to nearly $70,000 today. House Exec Summ at i.

[41] Teva Ltd., 2015 Annual Report (Form 20-F), Notes to Consolidated Financial Statements, F-64, https://www.sec.gov/Archives/edgar/data/818686/000119312516459785/d120587d20f.htm.

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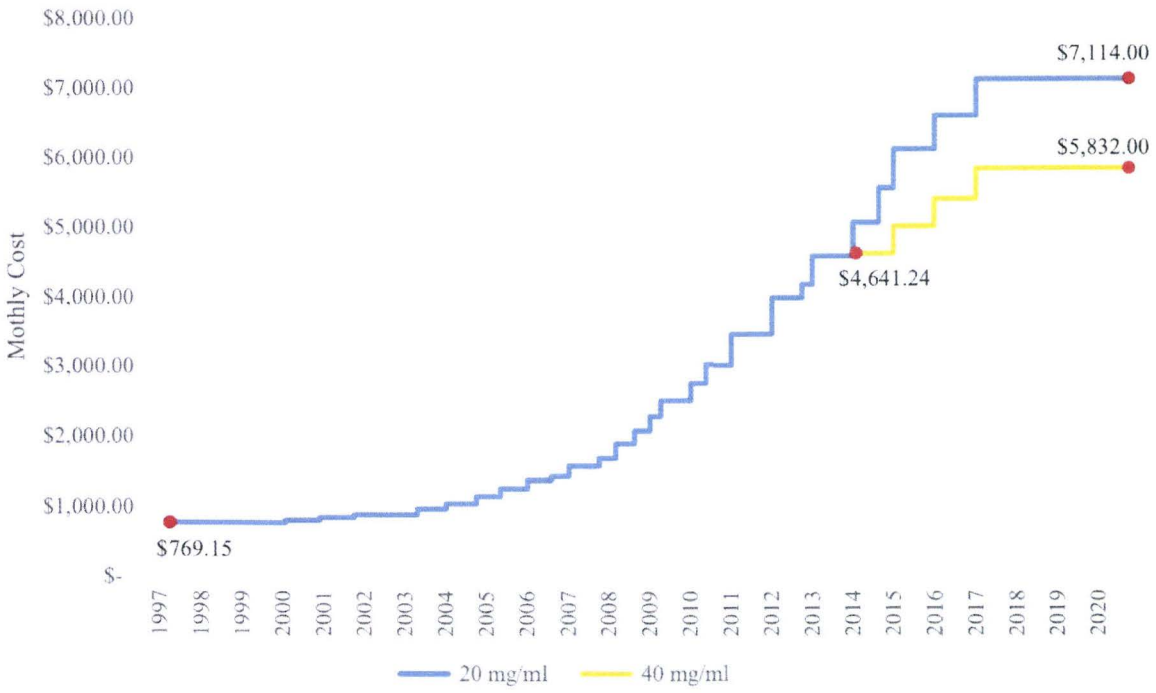
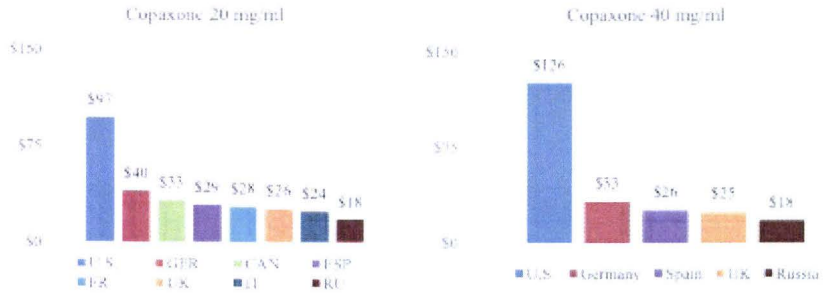
59. The following chart shows the increase in the monthly cost of Copaxone over time:



60. The prices Teva charged for Copaxone in the United States far exceeded the prices it charged in other countries. In 2015, the net price of Copaxone 40mg was $126 per day in the United States. In stark contrast, this same daily dosage was only $33 in Germany, $26 in Spain, $25 in the United Kingdom, and $18 in Russia. House Exec. Summ. at i. Internal Teva documents tracked these price differences:

Figure 4: 2015 Net Price Per Day of Therapy



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Indeed, the House Committee on Oversight found that Teva responded to "downward prices [sic] pressure in Europe" by raising the price of Copaxone in the United States by 60%. House Report at 5.

61. As the House Committee found, "[e]ven Teva's own employees could not afford Copaxone at its price." In one July 2018 exchange uncovered by House investigators, a Teva employee explained that she could no longer afford Copaxone because she would have to pay $1,673.33 out of pocket, far greater than the $12 it would have cost her to buy Mylan's generic version of the same drug. *Id.* at ii.

62. As U.S. consumers and health plans paid increasingly excessive amounts for this critical MS medication, Teva's executives obtained massive payouts. Top Teva Ltd. executives were paid more than $190 million between 2012 and 2017, a period during which Teva's net revenue from U.S. sales of Copaxone averaged $3 billion per year. House Report at 3-4. As the House Report explained,

> Teva's compensation policy makes clear that a significant portion of its executive compensation is based on "overall company performance measures," including net revenue and earnings. From 2012 to 2017, Copaxone's net U.S. revenue made up 15% of Teva's net worldwide revenue for all products. Teva's price increases for Copaxone had a direct impact on executive bonuses.

Id. The House Report also cited internal Teva emails between employees that "show that they were aware of the direct link between compensation and Copaxone sales." *Id.* at 5.

63. Teva's expenses did not come close to justifying its price increases. The House Oversight Committee concluded that the cost to manufacture Copaxone was "miniscule" (between 0.5% and 3% of the net price), and that cost "declined significantly" between 2013 and 2018 while Teva dramatically increased its price. *Id.* at 42.

64. The House Oversight Committee also found that "Teva invested only a small portion of its Copaxone revenue in further research and development to help Copaxone patients."

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Id. at v. Teva invested only $689 million in Copaxone related research and development since 1987, which is only 2% of the $34.2 billion in net U.S. revenue it obtained from Copaxone between 2002 and 2019. *Id.*

65. Moreover, the House Oversight Committee rebutted a common excuse offered by pharmaceutical companies: "Teva's internal data … suggest that its decades of price increases for Copaxone cannot be attributed to growing rebates or discounts provided to PBMs, pharmacies, health insurance plans, employers, or other payers." *Id.* at 41. Teva's net per patient price (after such rebates and discounts) increased from 2009 to 2017, by which point it exceeded $3800 per month ($45,600 per year). *Id.* at 41-42.

D. Pharmaceutical Industry Overview

66. Teva was able to dramatically increase the price of Copaxone without losing sales because it manipulated several unique aspects of the U.S. pharmaceutical market. The following section provides an initial overview of a few key concepts necessary to understanding Teva's misconduct.

67. ***Pharmaceutical Distribution chain*:** Pharmaceutical companies like Teva—also referred to herein as "drug companies" or "manufacturers"—develop, manufacture, market, and sell prescription drugs. Pharmaceutical companies sell their prescriptions drugs to wholesalers, who purchase drugs in bulk and distribute them to pharmacies and hospitals. Pharmacies typically purchase prescription drugs from wholesalers to dispense to consumers.

68. There are two main types of pharmacies: retail and specialty. Retail pharmacies dispense most common medications and include chain pharmacies (*e.g.*, Walgreens and CVS), pharmacies in grocery stores and other retailers (e.g., Walmart, and Costco), hospitals, and independently owned pharmacies. Specialty pharmacies dispense medications used to treat relatively rare or complex health conditions, as well as medications that require special handling, are administered through injection or IV, or require special instruction or follow-up care from a

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pharmacist or other health care professional. Copaxone is typically considered to be a specialty drug and is typically dispensed through specialty pharmacies.

69. ***Health Insurance:*** People with health insurance in the United States have either public or private health insurance. Public insurance refers to insurance provided by federal and state governments, including Medicare, Medicaid, the Children's Health Insurance Program, and health insurance provided through the Department of Veterans Affairs. Private health insurance refers to insurance that employers offer to their employees as well as insurance purchased directly by patients, including through health exchanges under the Affordable Care Act. As used herein, "private health insurance" includes health plans offered by cities, towns, municipalities or counties that provide health insurance for their employees. The majority of insured individuals in the United States (68.0 percent) have private health insurance, with the overwhelming majority of these individuals receiving health insurance through an employer.[42]

70. There are typically two forms of private health plans: insured plans and employer self-funded (or self-insured) plans. In the case of insured plans, plan members and/or employers pay premiums to an insurance company, which pools premiums to pay claims on behalf of plan members, and bears the risk or covering claims if the pooled premiums are insufficient to pay claims. In the case of self-funded plans, an employer provides health insurance for its employees by setting aside funds that are used to directly pay medical and prescription drug claims. While such an employer will typically contract with an insurance company that will provide administrative services, the employer pays claims and bears the risk for paying claims even if the cost of claims exceeds the funds it has set aside. As used herein, "payor" refers to the insurer (in the case of insured plans) or employer (in the case of employer self-funded plans) that is responsible for paying claims on behalf of plan members.

[42] Katherine Keisler-Starkey and Lisa N. Bunch, *Health Insurance Coverage in the United States: 2019*, U.S. Census Bureau (Sept. 2020), https://www.census.gov/content/dam/Census/library/publications/2020/demo/p60-271.pdf.

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71. ***Pharmacy Benefit Managers:*** A health benefit plan (or the insurance company that insures and/or administers the plan) typically enters into a contract with a pharmacy benefit manager ("PBM") that manages and administers prescription drug benefits on behalf of the plan. According to the PBM trade association, the Pharmaceutical Care Management Association ("PCMA"), PBMs administer prescription drug benefits for more than 266 million Americans. The three largest PBMs—CVS Caremark, Express Scripts, OptumRx—control 80% of prescription drug market (as measured by total adjusted claims). These PBMs administer prescription drug benefits for more than 200 million Americans, equaling roughly two-thirds of all insured Americans.

72. A PBM will create a network of pharmacies that will fill prescriptions at an agreed upon percentage discount from drug list prices. When a health plan member brings a prescription to a pharmacy, the pharmacy contacts the PBM, which will then process and adjudicate the prescription claim. This process entails determining whether the drug is covered under the member's plan and communicating to the pharmacy the portion of drug cost that will be covered by the plan and the portion that the pharmacy must collect from the plan member as coinsurance or copayment. The PBM pays the pharmacy for the plan's portion of the drug cost, later collecting payment from the payor for all drug claims paid on its behalf.

73. PBMs also design standard drug formularies that are used by their health plan clients. Formularies are, at base, lists of drugs that are available to members of a health plan. Formularies are typically "tiered," meaning that certain drugs are preferred over others for various medical conditions.

74. Many PBMs own or are otherwise affiliated with specialty pharmacies and plan members are often required to use the specialty pharmacy owned by or affiliated with their PBM. For example, members of plans serviced by Express Scripts are typically directed or required to fill their specialty prescriptions through Accredo or CuraScript, Express Scripts' wholly owned subsidiaries. Likewise, members of plans serviced by CVS are typically directed or required to

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fill their specialty prescriptions through CVS Specialty Pharmacy and members of plans serviced by OptumRx are typically directed or required to fill their specialty prescriptions through Optum Specialty Pharmacy (which was formerly known as BriovaRx).

75. ***Drug Pricing***: A drug's list price is set by the manufacturer and is the price at which the manufacturer sells the drug to wholesalers. This list price is reported publicly as the "Wholesale Acquisition Cost" ("WAC"), which is a single benchmark price that applies market wide in the United States. A related benchmark, "Average Wholesale Price" ("AWP"), reflects the average price paid by retailers to purchase a drug from wholesalers. AWP is typically set at 120% of the WAC. The prices paid by health plan payors and participants are set as a percentage of one of these benchmarks and are thus determined by the list price set by manufacturers.

76. ***Brand vs. Generics***: The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), governs the manufacturing, sale, and marketing of pharmaceuticals in the United States. Under the FDCA, a company that wants to sell a new drug must submit a New Drug Application ("NDA") to the FDA and provide scientific data demonstrating that the drug is safe and effective for a specific indication. *See id.* § 355(b)(1). The process to obtain FDA approval for an NDA is lengthy and very expensive.

77. To incentivize drug development, branded drug manufacturers protect their products from competition through an FDA-designated exclusivity period. New drugs are typically granted a five-year exclusivity period upon approval. Additionally, drug manufacturers are allowed to protect their new products through patents granted by the US Patent and Trademark Office. These patents are listed in the FDA's "Orange Book," *Id.* at § 355(b)(1), (c)(2), which lists all FDA-approved prescription drugs, their approved generic equivalents, and any patents that purportedly protect each drug. Exclusivity periods and patent protection periods often overlap, but can differ in lengths.

78. Drug patents typically last twenty years and can be obtained at any point in the drug discovery and development cycle for any number of chemical and product features. The

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FDA-exclusivity period is granted when a drug is first approved. Both the patent system and the exclusivity period create incentives for drug innovation by allowing drug innovators to recoup their initial research and development costs and make a substantial profit on top.

79. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, known commonly as the Hatch-Waxman Act ("Hatch-Waxman"), to facilitate competition from low-price generic drugs while maintaining the incentive for companies to research and develop new products. Hatch-Waxman permits generics to come to market as soon as brand drugs lose patent protection, and it encourages generic manufacturers to challenge the scope and validity of existing brand patents.

80. Once the FDA has approved a brand drug, Hatch-Waxman allows a generic manufacturer to obtain similar approval by filing an Abbreviated New Drug Application ("ANDA") specifying that the generic has the same active ingredient and is "biologically equivalent" ("bioequivalent") to the reference brand drug. The ANDA application process allows generic manufacturers to rely on a reference drug's original clinical studies, thereby reducing the cost and time necessary to bring a generic drug to market.

81. Price is the only material difference between generic drugs and their corresponding brand versions. Because generic versions of a corresponding brand drug product are commodities that are not differentiated through advertising or other means, the primary basis for generic competition is price.

82. Generic drugs, on average, cost 80-85% less than their brand-name counterparts.

83. It is widely known among pharmaceutical companies—and the Wall Street analysts and traders who determine their stock prices—that "generic drugs quickly take sales from brand drugs. Once a generic enters the market, a brand loses 44% to 90% of its market share within the first twelve months."[43]

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[43] Michael A. Carrier, et al., "*Citizen Petitions: Long, Late-Filed, and At-Last Denied*," 66 AM. U. L. REV. 305, 312 (Dec. 2016), https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1956&context=aulr

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E. Teva Used Sham Patent Litigation and Citizen Petitions To Delay Generic Entry

84. As part of its effort to frustrate and delay generic competition, Teva engaged in a decades-long campaign of filing objectively baseless patent litigation and citizen petitions as an anticompetitive weapon to interfere directly with the business relationships of competitors to block competition from generic versions of glatiramer acetate.

85. Teva initiated almost a dozen patent lawsuits seeking to enforce more than a dozen patents against companies who sought to introduce generic versions of glatiramer acetate. *See supra* ¶ 22(C) & nn. 9-10.

86. Teva also used the FDA's citizen petition process to delay the entry of generics. A citizen petition is intended for members of the public to raise safety concerns with the FDA. But, in this case, Teva was using citizen petitions to continue blocking generics from competing with Copaxone. Such petitions by brand drug manufacturers are "almost never granted," but they typically have the effect, absent some intervening event, of impeding market entry efforts of a generic for about 150 days, while the FDA considers the petition.[44]

87. As one leading scholar, Michael Carrier of Rutgers Law School, has explained: "Brand firms' filing of citizen petitions with the U.S. Food and Drug Administration ("FDA") has almost entirely slipped beneath the radar. In theory, citizen petitions could raise concerns that a drug is unsafe. But in practice they bear a dangerous potential to extend brand monopolies by delaying approval of generics, at a potential cost of millions of dollars per day."[45]

88. Citizen petitions cost little for the companies that file them. Consisting of boilerplate arguments, generally involving scientific data regarding a drug's manufacturing process, they are easy to file. Nor are there any consequences to filing frivolous petitions.[46]

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[44] Michael A. Carrier, et al., "Citizen Petitions: Long, Late-Filed, and At-Last Denied," 66 AM. U. L. REV. 305, 308; 347 (Dec. 2016), https://digitalcommons.wcl.american.edu/cgi/viewcontent. cgi?article=1956&context=aulr&httpsredir=1&referer=.

[45] *Id.* at 307.

[46] Carrier & Wander, "Citizens Petitions: An Empirical Study", 34 CARDOZA L. REV. 249, 279 (Oct. 2012) (citing The Generic Drug Maze: Speeding Access to Affordable, LifeSaving Drugs: Hearing Before the S. Spec. Comm. on Aging, 109th Cong. 6 (2006), https://www.aging.senate.gov/imo/media/doc/hr161hb.pdf).

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89. Between 2008 and 2015, Teva filed an astonishing eight Citizen Petitions with the FDA, which sought to block the approval of generic glatiramer acetate products.[47] Teva's first petition sought to have the FDA prevent any generic drug company from relying on the two abbreviated pathways commonly used for obtaining generic approval: the ANDA and the 505(b)(2). Both of these expedited procedures allow applicants to rely on the FDA's prior findings that the referenced drug, in this case Copaxone, is safe and effective. If this petition had been granted, it would have delayed the process for obtaining generic approval. Teva's first petition further requested that no generic, even if approved, should be given an AP rating, meaning no generic could be substituted for Copaxone under drug substitution laws.

90. Teva's subsequent petitions made similar arguments and sought to delay generic approvals and make the process for obtaining such approvals more burdensome, including by imposing requirements to conduct clinical studies and switching studies that went well beyond the traditional FDCA approval requirements for generic drugs. Professor Carrier discussed Teva's use of serial citizen petitions, calling it a "particularly glaring example of a company's aggressive use of the citizen petition process."[48]

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[47] Teva Neuroscience, Inc. Citizen Petition, No. FDA-2008-P-0529 (Sept. 26, 2008), Regulations.gov, https://www.regulations.gov/document/FDA-2008-P-0529-0001 (follow "Download" hyperlink); Teva Neuroscience, Inc. Citizen Petition, No. FDA-2009-P-0555 (Nov. 13, 2009), Regulations.gov, https://www.regulations.gov/document/FDA-2009-P-0555-0001 (follow "Download" hyperlink); Teva Neuroscience, Inc. Citizen Petition, No. FDA-2010-P-0642 (Dec. 10, 2010), Regulations.gov, https://www.regulations.gov/document/FDA-2010-P-0642-0001 (follow "Download" hyperlink); Teva Neuroscience, Inc. Citizen Petition, No. FDA-2012-P-0555 (June 4, 2012), Regulations.gov, https://www.regulations.gov/document/FDA-2012-P-0555-0001 (follow "Download" hyperlink for Teva Pharmaceuticals Ltd Citizen Petition); Teva Neuroscience, Inc. Citizen Petition, No. FDA-2013-P-1128 (Sept. 12, 2013), https://www.regulations.gov/document/FDA-2013-P-1128-0001 (follow "Download" hyperlink for Teva Pharmaceuticals Ltd Citizen Petition); Teva Neuroscience, Inc. Citizen Petition, No. FDA-2013-P-1641 (Dec. 5, 2013), Regulations.gov, https://www.regulations.gov/document/FDA-2013-P-1641-0001 (follow "Download" hyperlink for Citizen Petition from TEVA Pharmaceuticals); Teva Neuroscience, Inc. Citizen Petition, No. FDA-2014-P-0933 (July 2, 2014), Regulations.gov, https://www.regulations.gov/document/FDA-2014-P-0933-0001 (follow "Download" hyperlink for Citizen Petition From Teva Neuroscience Inc Redacted); Teva Neuroscience, Inc. Citizen Petition, No. FDA-2015-P-1050 (Mar. 31, 2015), Regulations.gov, https://www.regulations.gov/document/FDA-2015-P-1050-0001 (follow "Download" hyperlink).

[48] Michael A. Carrier, et al., "Citizen Petitions: Long, Late-Filed, and At-Last Denied," 66 AM. U. L. REV. 305, 345 (Dec. 2016), https://digitalcommons.wcl.american.edu/cgi/viewcontent.cgi?article=1956&context=aulr&httpsredir=1&referer=.

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91. These petitions were objectively baseless; there was no reasonable expectation of success on the merits. Every one of Teva's petitions was denied or withdrawn.[49]

92. Another concern with citizen petitions filed by brand drug companies is the proximity between when the FDA resolves the petition and when it approves the generic ANDA. "The concern in this scenario is that generic entry could be delayed because the FDA does not approve the ANDA until it resolves the citizen petition."[50] The FDA rejected Teva's final citizen petition, which challenged Sandoz's generic application, on April 16, 2015, the same day the FDA approved Sandoz's ANDA for 20mg Glatopa,[51] further raising concerns that Teva's citizen petition delayed the approval of Sandoz's ANDA.

93. Teva's efforts did not end when 20mg generic forms of glatiramer acetate entered the market. Rather, Teva fought to protect its market share by reformulating Copaxone to 40mg Copaxone and engaging in sham patent litigation. Teva filed at least five lawsuits for patent infringement against generic drug manufacturers who had submitted ANDAs for approval to

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[49] FDA Denial of Citizen Petition, No. FDA-2008-P-0529 (Mar. 25, 2009), Regulations.gov, https://www.regulations.gov/document/FDA-2008-P-0529-0007 (follow "Download" hyperlink); FDA Denial of Citizen Petition, No. FDA-2009-P-0555 (May 11, 2010), Regulations.gov, https://www.regulations.gov/document/FDA-2009-P-0555-0007 (follow "Download" hyperlink); FDA Denial of Citizen Petition, No. FDA-2010-P-0642 (June 8, 2011), Regulations.gov, https://www.regulations.gov/document/FDA-2010-P-0642-0008 (follow "Download" hyperlink); FDA Denial of Citizen Petition, No. FDA-2012-P-0555 (Nov. 12, 2012), Regulations.gov, https://www.regulations.gov/document/FDA-2012-P-0555-0005 (follow "Download" hyperlink); Teva Neuroscience, Inc. Withdrawal of Citizen Petition, No. FDA-2013-P-1128 (Jan. 3, 2014), Regulations.gov, https://www.regulations.gov/document/FDA-2013-P-1128-0005 (follow "Download" hyperlink); FDA Denial of Citizen Petition, No. FDA-2013-P-1641 (May 2, 2014), Regulations.gov, https://www.regulations.gov/document/FDA-2013-P-1641-0009 (follow "Download" hyperlink); FDA Denial of Citizen Petition, No. FDA-2014-P-0933 (Nov. 26, 2014), Regulations.gov, https://www.regulations.gov/document/FDA-2014-P-0933-0021 (follow "Download" hyperlink); FDA Denial of Citizen Petition, No. FDA-2015-P-1050 (Apr. 16, 2015), Regulations.gov, https://www.regulations.gov/document/FDA-2015-P-1050-0012 (follow "Download" hyperlink).

[50] Michael A. Carrier, et al., "Citizen Petitions: Long, Late-Filed, and At-Last Denied," 66 AM. U. L. REV. 305, 341 (Dec. 2016).

[51] Compare GLATOPA, DRUGS @ FDA, U.S. Food and Drug Administration, https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=090218 (toggle "Approval Date(s)…" dropdown tab for the approval date; toggle "Therapeutics Equivalents…" dropdown tab for reference to COPAXONE) (showing Sandoz-sponsored ANDA 090218, the only approved generic referencing COPAXONE, approved on April 16, 2015), with Teva Neuroscience, Inc. Citizen Petition, No. FDA-2015-P-1050-0001, at 2–4 (Apr. 1, 2015), Regulations.gov, https://www.regulations.gov/document/FDA-2015-P-1050-0001 (follow "Download" hyperlink) (denied on April 16, 2015, *supra* note 49).

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market and sell 40mg glatiramer acetate prior to the expiration of Teva's patents on 40mg Copaxone.

94. Like the citizen petitions, the patent lawsuits were objectively baseless. After a seven-day bench trial, the district court invalidated the patents on 40mg Copaxone because the change from the 20mg to 40mg formulation was "obvious" under 35 U.S.C. § 103(a), which provided that a patent may not be obtained "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art." *See In Re: Copaxone Consol. Cases*, 906 F.3d 1013, 1024 (Fed. Cir. 2018) (affirming the invalidation of Teva's 40mg Copaxone patents). No reasonable litigant could realistically expect success on the merits of the lawsuit centering on the obvious change—and particularly not an experienced and frequent litigant such as Teva.

95. The trial court found that the patents Teva sought to enforce were "nothing more than 'life-cycle management'—an attempt to continue to monopolize a multi-billion dollar market for a blockbuster drug."[52]

96. In other words, Teva misused patent litigation to interfere with competitors' business relationships and stifle competition.[53]

97. In February 2020, Teva engaged in yet another attempt to circumvent the drug substitution laws and thus avoid generic competition. Teva sought to have the FDA reclassify Copaxone as a "biological product" under the Public Health Service Act ("PHSA"), 42 U.S.C. § 201 *et seq.*, rather than as a "drug" under the Food, Drug, and Cosmetics Act ("FDCA"), 21 U.S.C. § 301 *et seq.* Teva claimed this change was made necessary by the Biologics Price Competition and Innovation Act of 2009 ("BPCIA") and subsequent amendments, which altered

[52] *In re Copaxone Consol Cases*, No. 14-1171, 2017 WL 401943, at *24 (D. Del. Jan. 30, 2017).
[53] *See id.* (noting Teva's objective for lifecycle management "to 'fight generics.'").

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the definition of "biological product" to include "proteins" and other analogous therapeutic products and required such products to be reclassified by March 23, 2020.

98. Teva sought this reclassification because it would have allowed Copaxone to avoid generic substitution under state drug substitution laws. Although all states allow (and in some cases require) pharmacists to substitute generic versions for a prescribed brand name drug, the same is not the cases for "biological products." Some states do not allow any substitution of biological products. Those that do allow substitution of biological products require the generic to have satisfied the FDA's heightened "interchangeability" requirement, which applies to biological products but not to drugs. 42 U.S.C. § 262(h)(3), (k)(3)(A)(ii), (k)(4).

99. Teva knew that no generic had been declared "interchangeable" with Copaxone. Teva also knew that the FDA's process of evaluating interchangeability was onerous because, among other things, the FDA generally requires a clinical "switching study" to evaluate whether switching between the brand and the generic is riskier than using only a single product.

100. Teva thus knew that, at a minimum, reclassification of Copaxone as a "biological product" would delay any further generic substitution and possibly end it altogether. As Teva USA's Vice President for Specialty Product Marketing, Dalton Tomlinson, stated in a sworn declaration,

> [I]f COPAXONE were deemed to be licensed as a biological product rather than approved as a drug, then in nearly all cases, a prescription for "COPAXONE" would be filled with Teva's product, rather than the generic that is currently substituted.... Accordingly, because prescriptions written for "COPAXONE" would be filled with Teva's product, Teva's market share would increase unless prescribers' behavior changed significantly.[54]

[54] Declaration of Dalton Tomlinson at ¶¶ 15-16, *Teva Pharm USA, Inc et al v U S Food and Drug Admin et al.*, 1:20-cv-00808-BAH, (D.D.C. July 16, 2020) ECF No. 41-2.

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101. After the FDA refused to reclassify Copaxone, Teva filed suit against the FDA. In dismissing Teva's claims, Chief Judge Beryl A. Howell of the District of Columbia District referred to Teva's conduct as "yet another effort to stifle Copaxone competitors."[55]

F. Teva's Illegal, Anticompetitive, Unfair, and Deceptive Acts to Stifle Competition from Approved Generics

102. On September 30, 2020, the House Committee on Oversight and Reform ("House Committee") released findings from its investigation of Teva's pricing of Copaxone, which were based on the Committee's review of more than 300,000 pages of internal documents, communications, and data. House Exec. Summ. at i. The House Committee's report details how Teva utilized numerous anticompetitive tactics to prevent approved generic forms of glatiramer acetate from fairly competing with Copaxone even after they entered the market. As a result, Teva caused health plan payors to continue to pay for Copaxone despite its inflated price and despite the availability of lower-cost generics.

103. The House Committee found that Teva Ltd. specifically "targeted the U.S. market for price increases while maintaining or cutting prices for the rest of the world." *Id.* Indeed, the House Committee uncovered internal documents in which Teva Ltd. emphasized that one of its key strengths was its ability to "increase prices successfully," which was "influenced heavily by U.S. being allowed to hike prices." *Id.* Teva Ltd. directly compared the pricing dynamics in the United States and Europe, noting that "Premium prices are available" in the United States, while prices in Europe are "much lower." House Report at 7.

104. Teva has conspired with specialty pharmacies, non-profit foundations, PBMs, physicians, and other persons and entities throughout the U.S. healthcare system to effectuate an ongoing campaign to cause health plan payors to pay for excessively priced Copaxone instead of more affordable generics. Teva and its co-conspirators achieved this by manipulating the

[55] Memorandum Opinion at 1, *Teva Pharm USA, Inc. et al v U S Food and Drug Admin et al.*, 1:20-cv-00808-BAH, (D.D.C. Dec. 31, 2020) ECF No. 54.

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purchasing decisions of health plan members and the prescribing decisions of physicians, and by restricting the ability for pharmacies to fill prescriptions with lower-cost generics. Because Teva was able to induce health plan payors to continue purchasing Copaxone despite its high price, Teva was able to continue to increase and maintain the high price of Copaxone even after generic alternatives entered the market.

105. As detailed below, these efforts were multi-faceted. First, Teva and its co-conspirators executed an illegal, anticompetitive, and deceptive copay assistance campaign, which induced health plan members to purchase Copaxone instead of generics by subsidizing members' out of pocket Copaxone costs, leaving health plan payors to foot the bill for the more expensive drug. Second, Teva and its co-conspirators executed a product hop: when the original formulation of Copaxone was nearing the end of its patent exclusivity, Teva altered the dosage and coerced and manipulated patients and doctors to switch to the new dosage, which enjoyed the benefit of Teva's improper claim to extended patent exclusivity; this allowed Teva to avoid drug substitution laws, under which pharmacists would have filled Copaxone prescriptions with lower-cost generics. Finally, Teva conspired with specialty pharmacies, PBMs, and doctors to cause prescriptions to be written for and filled with Copaxone instead of available, lower-costs generics.

1. Teva's Deceptive and Illegal Use of Copay Assistance

106. Teva conspired with a specialty pharmacy, non-profit foundations, and other entities to implement an anticompetitive scheme to undermine and circumvent health plan cost-sharing provisions, which would have fostered price competition with generics and served as a significant check on its price hikes.

a. Patient Cost-Sharing Obligations Serve as a Check on Drug Costs

107. Health plans, including both private and Medicare plans, use deductibles, copayments, coinsurance, and other cost-sharing mechanisms to limit health care spending. These payments, which are referred to generally as "cost-sharing payments" or "co-pays," are

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amounts health plan members pay out-of-pocket when filling a prescription at a pharmacy. These provisions serve to better align the incentives of health plan members and health plan payors. As previously explained, plan members, and not health plan payors, decide whether to purchase medications and which medications to purchase. When members share in the cost of prescription drugs, they become sensitive to price and have an incentive to minimize costs, which, in turn, minimizes the costs incurred by health plan payors, who still pay the majority of the cost of prescription drugs.

108. Accordingly, these provisions facilitate price competition and serve as a check on the price of health care. Cost-sharing mechanisms create incentives for members to select the most affordable form of any given treatment, particularly as health care becomes more expensive. This, in turn, limits the health plan payor's spending. For example, members who have to pay 20% coinsurance would be more willing to buy a drug if it cost $100, with a $20 out-of-pocket payment, than if it cost $1000, with a $200 out-of-pocket payment. Likewise, a member is more likely to favor a generic drug for which they have to pay a $20 copayment than a brand name drug for which they have to pay a $50 copayment. These cost-share obligations provide critical incentives for members to prefer lower-cost generic drugs and for drug manufacturers to price their products based on market forces, since fewer members will purchase (and thus cause their health plan payors to pay for) drugs as drug prices increase.

109. Because Teva charged $70,000 for an annual course of Copaxone, patients seeking to purchase Copaxone potentially faced thousands of dollars in annual deductible, co-insurance, and other forms of cost-sharing payments.

b. Teva Sought to Circumvent These Price Checks

110. Teva knew that if members of private health plans were exposed to high cost-sharing obligations, substantially fewer patients would have purchased Copaxone and Teva would have been forced to lower prices or lose sales.

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111. Instead of lowering the price to make Copaxone more affordable, Teva instead devised a scheme to bypass these price controls by paying the cost-sharing obligations on behalf of health plan members. With respect to private health plans, Teva provided "coupon" cards directly to plan members. When a member went to a pharmacy to fill a Copaxone prescription, the pharmacy would accept the coupon from the participant in lieu of collecting the participant's cost-sharing obligation, and Teva would pay the pharmacy for the value of the coupon. The health plan member would obtain Copaxone, having paid little or nothing out of their own pocket. Indeed, private health plan members would pay *less* for Copaxone than they would have paid for lower-priced generics. Because they were not exposed to the increasing price of Copaxone, these health plan members continued to purchase Copaxone even as the price for Copaxone skyrocketed.

112. This scheme came at great expense to health plan payors like Plaintiffs. By using this coupon system instead of lowering the price of Copaxone, Teva shielded the decisionmakers (i.e., plan members) from the impact of Copaxone's excessive price, thereby inducing further sales, all while exposing the health plan payors, who pay the majority of any drug's costs, to the ever-increasing list price.

113. Teva offered this "coupon" service, known as "Copaxone Co-Pay Solutions," as part of its "Shared Solutions" patient-services program. Shared Solutions provided Copaxone patients with injection training and other educational services in addition to these "coupons." According to Teva, Shared Solutions was "dedicated to getting and keeping patients on" Copaxone. Teva assigned each patient a case manager who, among other things, would help them obtain copay coupons.

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114. Teva was able to quickly build direct relationships with patients because physicians who prescribed Copaxone typically submitted enrollment forms to Shared Solutions on behalf of each new Copaxone patient.[56]

115. By insulating members of private plans from price increases, Teva caused private health plan payors to pay for Copaxone despite its high cost and to continue paying for Copaxone despite cost increases.[57] A 2005 HHS OIG Advisory Bulletin explained the harm posed by these private co-pay assistance programs:

> Subsidies provided by traditional pharmaceutical manufacturer PAPs [patient assistance programs] have the practical effect of locking beneficiaries into the manufacturer's product, even if there are other equally effective, less costly alternatives (and even if the patient's physician would otherwise prescribe one of these alternatives) .... [C]ost-sharing subsidies can be very profitable for manufacturers, providing additional incentives for abuse. So long as the manufacturer's sales price for the product exceeds its marginal variable costs plus the amount of the cost-sharing assistance, the manufacturer makes a profit. These profits can be considerable, especially for expensive drugs for chronic conditions.[58]

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[56] Complaint ¶ 48, *United States v Teva Pharmaceuticals USA, Inc* , No. 20-cv-11548 (D. Mass. Aug. 18, 2020), ECF No. 1 ("Gov't Compl."). Exhibits to the Gov't Compl. are referred to herein as "Gov't Exs."

[57] Even where plans imposed fixed-dollar copayment obligations, by paying these copay amounts on behalf of members, Teva induced payors to pay for prescriptions that might not have been purchased had participants been required to comply with their copay obligations. This is particularly true where plans impose a higher copayment obligation for brand drugs like Copaxone and a lower copay for generic versions of the same drug. In these cases, participants would be expected to favor the lower-cost generic but for Teva's intervention to effectively waive the higher brand drug copayment.

[58] HS-OIG's 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70626 (Nov. 22, 2005).

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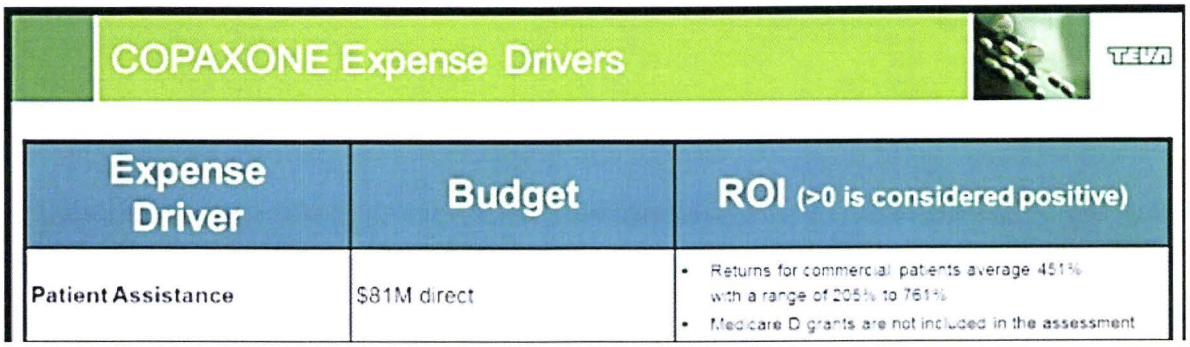
116. Teva's average return on investment on these payments to private plan members was 451%, meaning that for every $100 Teva spent on "co-pay assistance," Teva obtained $451 in profits. House Exec. Summ. at iii; House Report at 13. In fact, in 2014 alone, Teva collected $257.5 million in net revenue from its $54.6 million in private copay assistance expenditures. *Id.* at iv.



COPAXONE Expense Drivers

TEVA

Expense Driver	Budget	ROI (>0 is considered positive)
Patient Assistance	$81M direct	• Returns for commercial patients average 451% with a range of 205% to 761% • Medicare D grants are not included in the assessment

117. These are additional Copaxone sales that would not have occurred unless Teva either lowered its prices or relieved private plan members of their cost-sharing payments. Indeed, the House Committee cited Teva's 2008 Copaxone Work Plan, which "estimated that the company would spend approximately $70 million on 'Private insurance Financial Assistance' between 2008 and 2011 and that this expenditure would result in the sale of 198,930 units of Copaxone that otherwise would have been lost." House Report at 13. The House Committee described a 2017 Teva strategy presentation that "explained that the commercial co-pay programs benefited Teva's sales by ensuring that patients stayed on Copaxone over time." *Id.* at 14.

c. Teva Doubled Down with an Elaborate Medicare Kickback Scheme

118. Although Teva's coupon program allowed it to side-step cost-sharing obligations with respect to members of private health plans, Teva knew it could not pursue this direct coupon strategy with respect to Medicare recipients and members of other federal health plans. Federal law prohibits pharmaceutical manufactures from subsidizing the co-insurance or other cost-sharing obligations of members of federal health plans. This obstacle was significant, as

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Teva documents reflect that Medicare recipients accounted for 27% of Copaxone patients. House Report at 21.

119. Moreover, this obstacle impacted not only the price Teva could charge members of Medicare plans and other federal health plans, but also the price Teva could charge members of private health plans. Teva sets a single Copaxone list price that applies to virtually all Copaxone purchases in the United States, including for Copaxone prescribed to both Medicare recipients and members of private health plans.

120. Teva thus faced the following choice: if Teva kept prices high (or continued to increase prices), it would maintain (or increase) its revenues from sales to private health plan members but lose sales to members of federal health plans; if Teva lowered prices, it would maintain sales to members of federal health plans but obtain lower revenue from sales to private health plan members.

121. But if Teva could figure out a way to cheat the system to subsidize cost-sharing obligations of Medicare recipients and other members of federal health plans, Teva could keep the single list price high for all health plan payors—private and public—without losing sales. That is precisely what Teva did.

(i) Teva Devised an Illegal Kickback Scheme

122. The United States filed suit against Teva in August 2020 alleging violations of the Anti-Kickback Statute and the False Claims Act.

123. The Anti-Kickback Statute prohibits pharmaceutical manufacturers from subsidizing co-insurance and other cost-sharing obligations incurred by Medicare recipients. 42 U.S.C. § 1320a-7b(b). As the HHS OIG explained in a 2005 Advisory Bulletin, if drug manufacturers were permitted to pay the co-pays of Medicare recipients, they could "eliminat[e] a market safeguard against inflated prices."[59]

[59] HHS-OIG's 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70625-27 (Nov. 22, 2005).

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124. Any Medicare claim "that includes items or services resulting from a violation of [the anti-kickback statute] constitutes a false or fraudulent claim for purposes of [the False Claims Act]." 42 U.S.C. § 1320a-7b(g). Claims submitted to Medicare that are the result of violations of the anti-kickback statute—including claims for prescription drug purchases induced by the illegal subsidization of patient cost-sharing obligations—are *per se* false or fraudulent claims within the meaning of 31 U.S.C. § 3729(a).

125. Teva funneled over $300 million through non-profits that served as pass-through vehicles so that Teva could subsidize Medicare cost-sharing obligations for Copaxone. As the government detailed in its 59-page complaint based on its extensive review of documents, "Teva knowingly and willfully violated the anti-kickback statute, 42 U.S.C. § 1320a-7b(b), by paying over $300 million to two third-party foundations, Chronic Disease Fund and The Assistance Fund, to cover the Medicare co-pay obligations of Copaxone patients. This conduct generated hundreds of millions of dollars in false claims to Medicare and a corresponding amount of revenue for Teva."[60] A copy of the government's complaint is attached hereto as Exhibit 1.

126. The government provided a detailed list of the dozens of payments Teva made to Chronic Disease Fund and The Assistance Fund, a copy of which is attached hereto as Exhibit 2. Although these entities ostensibly provided financial assistance to help patients pay co-pays for any MS drug on the market, Chronic Disease Fund and The Assistance Fund in fact conspired with Teva to ensure that the "donations" Teva made to these entities would be used to provide co-pay assistance exclusively for patients purchasing Copaxone.

(ii) Teva Conspired with Multiple Entities to Execute Its Illegal Kickback Scheme

127. To facilitate this scheme, Teva conspired with a specialty pharmacy, Advanced Care Scripts, Inc. ("Advanced Care"), to which Teva referred Copaxone patients who either had or were eligible for Medicare coverage. Advanced Care would then arrange for the patients to

[60] Gov't Compl. ¶ 1.

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obtain co-pay assistance from Chronic Disease Fund and The Assistance Fund by sending batch files to each entity reflecting the names of Copaxone patients.

128. Advanced Care reported to Teva the number of Copaxone patients that were referred to Chronic Disease Fund and The Assistance Fund . Gov't Exs 36-43 (e-mails from Advanced Care to Teva reporting Copaxone patients receiving co-pay assistance from Chronic Disease Fund and The Assistance Fund). Chronic Disease Fund and The Assistance Fund also regularly provided Teva with the per-patient grant amounts. Gov't Exs 30-35.[61] Teva then used this information during its annual budgeting process to determine the amount of "donations" it paid to Chronic Disease Fund and The Assistance Fund to fund the co-pay assistance. The Government recently uncovered and disclosed detailed budget spreadsheets that reflect how Teva's "donations" to Chronic Disease Fund and The Assistance Fund were based specifically on the foundation grant amounts and Teva's projections of the cost-sharing payments faced by the Medicare recipients who were referred to Chronic Disease Fund and The Assistance Fund . Gov't Exs. 44-48. In other words, the amounts of Teva's donations each year were based on its calculation of the amount Chronic Disease Fund and The Assistance Fund would need to specifically fund Copaxone co-pay assistance for Medicare recipients. After Teva made these payments, Advanced Care provided it with confirmation that the donations covered the Copaxone patients' costs.

129. Teva would further use information received from Advanced Care on new patients awaiting copay assistance and would make supplemental "donations" to Chronic Disease Fund and The Assistance Fund that were earmarked to fund assistance for these new patients. The government recently disclosed a series of Teva e-mails and documents the reflect the following process: Advanced Care would share with Teva how many new patients were awaiting co-pay assistance and The Assistance Fund would tell Teva the average Medicare co-

[61] *See also* Affidavit of Edward H. Hensley ¶ 13, *United States v Teva Pharmaceuticals USA, Inc* , No. 20-cv-11548 (D. Mass. Aug. 18, 2020), ECF No. 1-2 ("Hensley Aff."), attached hereto as Exhibit 3.

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pay grant for a Copaxone patient at the time. Teva would then multiply those two figures and add an amount for The Assistance Fund's administrative fees. Teva would then tell Advanced Care that it intended to pay this amount to The Assistance Fund. Upon receipt of this payment, TAF would re-open its co-pay fund to new applicants and Advanced Care would provide a batch file of names of the new Copaxone patients, who were admitted to the program. *See* Gov't Compl. ¶ 90 (citing testimony of Teva's Director of Customer Resources, Denise Lynch, that this "was the normal way it was done."); Hensley Aff. ¶¶ 13-14; Gov't Exs. 42, 51-78).

130. Advanced Care's founder, Edward Hensley, stated in a sworn affidavit that since at least 2008, he "understood that Teva was purposefully utilizing Advanced Care and structuring its donations to Chronic Disease Fund in a manner the essentially ensured that such donations would benefit only Copaxone patients, and not patients who had been prescribed competitor MS medications." Hensley Affidavit ¶ 3. Hensley explained that he and Teva's Director of Customer Resources, Denise Lynch, together identified Chronic Disease Fund as a foundation that would work with their scheme, including because its "intake process … was designed to ensure that monies that a pharmaceutical manufacturer donated would flow through to that manufacturer's patients." *Id.* ¶ 5. In a 2007 email recently disclosed by the Government, Hensley instructed his Advanced Care colleagues that "particular manufacturer funds [should] go to their own drugs as [that was] what … the intent of the project was originally." Gov't Ex. 8.

131. Hensley and his co-founder of Advanced Care, Jeff Spafford, left Advanced Care in 2009 and founded The Assistance Fund, a foundation modeled after Chronic Disease Fund. Lynch inquired whether The Assistance Fund would function similarly to Chronic Disease Fund, and Hensley assured her and others at Teva that "The Assistance Fund would provide all of the advantages that Chronic Disease Fund did—including accepting 'batch files' of patients from a manufacturer's 'hub' or preferred specialty pharmacy, not utilizing waiting lists, and accepting donations at any time during the year." Hensley Affidavit ¶ 10. As Hensley explained, "I made sure that Ms. Lynch understood that Teva effectively would be able to use The Assistance Fund

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as it had Chronic Disease Fund: essentially, as a 'pass-through' donation vehicle to get Teva monies into the hands of Copaxone patients." *Id.* When Teva began paying The Assistance Fund to provide Copaxone co-pay assistance, Hensley and The Assistance Fund accepted the batch files from Advanced Care "despite knowing that Advanced Care had purposefully and strategically structured the batch file to benefit Copaxone patients rather than to fairly reflect Advanced Care's population of financially needy MS patients." Hensley Affidavit ¶ 12.

132. Hensley and Spafford also founded a for-profit business called AssistRx. Although Advanced Care continued to participate in the scheme after Hensley and Spafford departed, in February 2015, AssistRx assumed Advanced Care's role of arranging Medicare co-pay assistance for Copaxone patients referred by Teva. In other words, by at least 2015, the same individuals—Hensley and Spafford—operated both the foundation providing the Copaxone co-pay assistance and the corporation serving as the conduit between Teva and the foundation.

133. Advanced Care and AssistRx were rewarded for their participation in the scheme. Both entities obtained millions in service fees paid by Teva. Additionally, Advanced Care, a specialty pharmacy, profited from additional sales of Copaxone to Medicare recipients. After Advanced Care referred patients to Chronic Disease Fund and The Assistance Fund for co-pay assistance, Advanced Care was the pharmacy that dispensed Copaxone to the majority of such patients.

134. Teva took steps to ensure its "donations" would be used exclusively for Copaxone and not for other MS medications. Teva timed its payments to Chronic Disease Fund and The Assistance Fund to coincide with Advanced Care's submission of the batch files reflecting Copaxone prescriptions. Lynch told Hensley that she would not authorize donations to another co-pay foundation because it had previously "burned" her by using Teva donations to cover co-pays for other drugs. Hensley Aff. ¶ 4. Hensley further stated that "Ms. Lynch told me, in sum and substance, that Teva would only authorize a donation to a charity that could provide Teva

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reasonable assurance that the donation would exclusively (or at least predominately) benefit Copaxone patients." *Id.*

135. Advanced Care, as the specialty pharmacy that filled the majority of Copaxone prescriptions for patients referred to Chronic Disease Fund and The Assistance Fund , submitted false claims records when it filled Copaxone prescriptions that it knew were induced by Teva's illegal kickbacks. The insurers who sponsor and contract with the government to provide Medicare plans enter into subcontracts with pharmacies who fill prescriptions for Medicare recipients. When a pharmacy dispenses a drug to a Medicare recipient, the pharmacy submits an electronic record of the claim, known as a Prescription Drug Event ("PDE"), to the Centers for Medicare & Medicaid Services ("CMS"). Pharmacies and other "downstream" or "related" entities that subcontract with Medicare plans are required to comply with the False Claims Act and Anti-Kickback Statute, and all other federal laws, regulations, and CMS instructions. 42 C.F.R. §§ 423.505(h)(1), (i). CMS regulations require that the pharmacies and other "downstream" entities that generate and submit PDEs must certify that the PDEs are true, accurate, and complete and that the PDE data is the basis for obtaining federal reimbursement for the healthcare products or services reflected therein. *Id.* §§ 423.505 (i), (k). In conjunction with each Copaxone prescription it filled to a patient using copay assistance from Chronic Disease Fund and The Assistance Fund , Advanced Care certified false claims and PDEs because it knew the claims were induced by illegal kickbacks. The government submitted representative samples of PDEs reflecting false claims for which Medicare provided reimbursement for the purchase of Copaxone by a Medicare recipient who used an illegal copay subsidy from Teva via Chronic Disease Fund and The Assistance Fund . A copy of the government's exhibit reflecting these representative claims is attached hereto as Exhibit 4.

(iii) Teva Calculated Its Return on Investment

136. The purpose of this scheme was clear: Teva subsidized the cost-sharing payments of Medicare recipients to cause Medicare to pay for Copaxone prescriptions that otherwise

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would not have been filled because recipients could not afford their cost-sharing payments. As the government explained, "Teva intended the payments to ensure that Copaxone patients never faced the steep prices that Teva charged for its drug, thus inducing the patients, including Medicare patients, to purchase the drug." Gov Compl. ¶ 2. The government further explained that "Teva knew that, if it did not use Chronic Disease Fund and The Assistance Fund to subsidize Medicare patients' co-pays for Copaxone, substantially fewer patients would use Copaxone and Teva's revenue would suffer." Gov Compl. ¶ 6.

137. The government cited a statement from Katie Hiett, Teva Neuroscience's Director of Finance and Planning, to Felicia Ladin, Teva USA's Vice President of Finance, explaining that "[n]ot funding these patients has a direct and immediate impact on units [sold]." Gov Compl. ¶ 6; Gov't Ex. 13 at 1. A Teva marketing director, Mike Sheehy, sent an e-mail to his boss in December 2012 reporting that he had "provided Denise [Lynch] the direction to move forward" with additional donations in 2013 "because not doing so directly impacts the topline with existing patients." Gov't Ex. 14 at 1. In 2015, a Teva Financial analyst, Alejandro Castro, explained to Teva's VP of Finance, David Loughery, that Teva would need to pay additional "donations" of $5 and $8 million "to avoid losing an estimated 1,500 Medicare Patients." Gov't Ex. 16 at 2. Castro also quantified the impact on total revenue to Teva, noting that a reduction of $6.3 million in annual "donations" "may be a risk to Net Sales of approximately $5.8M *per month*." *Id.* at 1 (emphasis added).

138. Internal documents uncovered by the House Committee further reflect that Teva expressly understood these illegal payments to the foundations to be an "investment" in future Copaxone sales. For example, Teva's 2008 Copaxone Work Plan estimated that Teva would spend approximately $97 million on "Medicare Financial Assistance between 2008 and 2011, which would result in the sale of an additional 155,113 units of Copaxone worth nearly $300 million. House Report at 15. In other words, the House Committee calculated that Teva anticipated receiving a 200% return on its "investment" because the payments to the foundation

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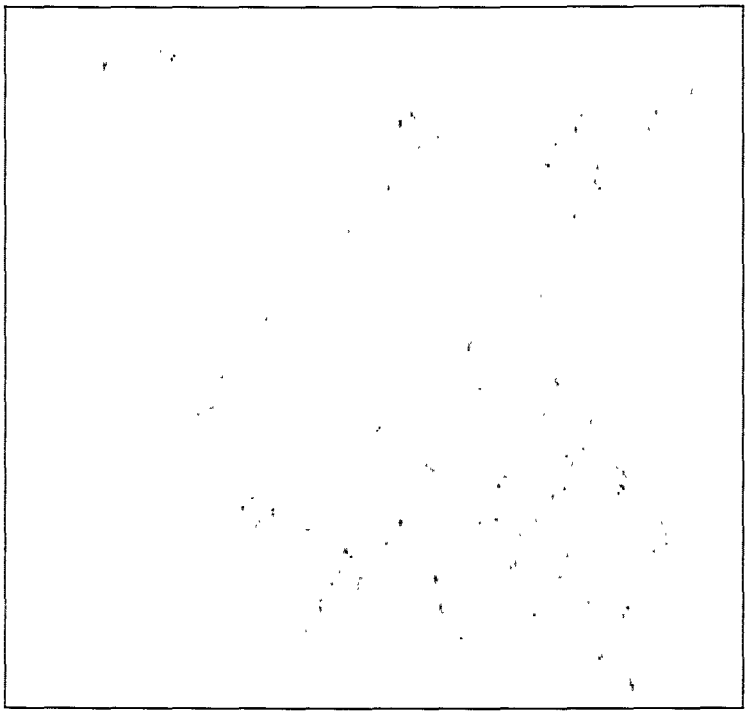
would cause Medicare to purchase more than 150,000 units of Copaxone that would not have been purchased had Medicare recipients been exposed to their cost-sharing payments. *Id.*

139. The government also uncovered handwritten notes from a Teva Patient Services manager, Jenny Jackson, reflecting an "ROI" analysis of these "donations." The notes show that Teva knew in 2010 that a $28 million "expense" would result in 4,800 additional Copaxone patients generating more than $114 million in net revenue. Gov't. Compl. ¶ 65.



140. Teva raised the amounts of its "donations" in lockstep with its increases to the price of Copaxone to ensure that Medicare recipients remained insulated from their price hikes, causing Medicare to continue to pay more as the price of Copaxone skyrocketed. For example, in a November 15, 2011 e-mail, Katie Hiett forwarded Felicia Ladin a discussion of a potential price increase and wrote: "I discussed the need for Patient Assistance with Denise [Lynch] and incremental price increases of 9.9%/5% over planned amount of 8.9% would cause a potential patient assistance increase of $4M-$5M across all of the Copaxone patient assistance programs."

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Gov't Ex. 18 at 1. As Hiett later testified: "Well, if you raise the price of your product, the patient's coinsurance for out of pocket goes up as well." Gov't Compl. ¶ 62.

141. That these payments to Chronic Disease Fund and The Assistance Fund were not gratuitous donations but instead self-interested pass-through payments to Copaxone patients is further underscored by the fact that Teva's tax department wrote in a July 2013 memorandum that "[t]he payments … are made with the expectation of financial return commensurate with the amount donated and should therefore be deducted as business expense[s]." Gov't Ex. 19 at 1. Teva executives repeatedly referred to these payments as "Copaxone donations" rather than disinterested donations to help support any MS treatment. Gov't Exs. 20-22.

(iv) Teva Management Approved the "Donations"

142. Teva's senior executives—including Teva Ltd.'s corporate officers—were required to approve the "Copaxone donations" to Chronic Disease Fund and The Assistance Fund . For example, a September 23, 2015, email addressed a "request for Copaxone donations from [The Assistance Fund]" and stated Teva would need "written documentation of approval at the appropriate approval authority," listing the following "Approval Authority Levels":

Gov't Ex. 3 at 6.

Approval Authority Levels
$0.5M Sr. Director
$1M VP
$5M SVP (Larry Downey in the past)
$15M TEC members, Rob Koremans
$25M CFO (Eyal Desheh)
$25M CEO (Erez Vigodman)

Rob Koremans, Teva LTD's President and CEO for Global Specialty Medicines, is listed as needing to approve donations between $5 and $15 million. House Report at 16. Teva LTD's CFO, Eyal Desheh, was required to approve donations between $15 and $25 million, and Teva Ltd.'s CEO, Erez Vigodman, as required to approve donations over $25 million. *Id.*

143. As the House Committee explained, "[g]iven the size of Teva's donations to third-party foundations, this policy would have required them to have been approved by the

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company's Executive Committee, Chief Financial Officer (CFO), or Chief Executive Officer (CEO)." House Report at 16. Hensley stated in his affidavit that he "understood from [his] conversations with Ms. Lynch that she needed approval from Teva's senior management, including Teva Ltd. management in Israel, to make the larger donations and that she might not obtain that approval unless she were able to demonstrate that the donations would substantially go to Copaxone patients." Hensley Affidavit ¶ 7.

144. The Department of Justice uncovered e-mails reflecting how Mr. Deshe and Mr. Koremans approved specific Copaxone donations for Medicare recipients, including approving a $25 million donation on January 10, 2015. Gov't Ex. 21. *See also* Gov't Ex. 22 (February 4, 2015 approval by Rob Koremans); Gov't Ex. 24 (January 19, 2017 request to Rob Koremans for approval of $38 million in Medicare "donations").

(v) Teva Knew It Acted Unlawfully

145. Teva knew that that it could not use Chronic Disease Fund and The Assistance Fund as pass-through vehicles to circumvent the Anti-Kickback statue. A 2005 HHS-OIG Advisory Bulletins expressly explained that although drug manufacturers may make donations to a "*bona fide* independent charity" patient assistance program, such charity "*must not function as a conduit for payments by the pharmaceutical manufacturer to patients*" and the manufacturer should not "solicit or receive data from the charity that would facilitate the manufacturer in correlating the amount or frequency of its donations with the number of subsidized prescriptions for its products." HS-OIG's 2005 Special Advisory Bulletin on Patient Assistance Programs for Medicare Part D Enrollees, 70 Fed. Reg. 70623, 70625-27 (Nov. 22, 2005).

146. This Bulletin detailed the OIG's concerns with the precise type of scheme implemented by Teva:

> We are concerned that pharmaceutical manufacturers may seek improperly to maximize [its] profits by creating sham "independent" charities to operate PAPs; by colluding with independent charity programs to ensure that the manufacturer's contributions only or primarily benefit patients using its products ….

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Id. at 70626*; see also* HHS-OIG's 2014 Supplemental Special Advisory Bulletin, Independent Charity Patient Assistance Programs, 79 Fed. Reg. 31120, 31123 (May 30, 2014) (explaining that "actions by donors to correlate their funding … with support of their own products … may be indicative of a donor's intent to channel its financial support to copayments of its own products, which would implicate the anti-kickback statute.").

147. Teva's knowledge of these Advisory Bulletins is demonstrated by the fact that the 2005 Bulletin was expressly referenced in its original contract with CDF, Gov't Ex. 25, and the requirements of the Bulletin were reiterated in an OIG advisory opinion subsequently obtained by CDF.[62] Moreover, when Teva began paying TAF in 2010, Hensley sent Lynch a copy of the advisory opinion TAF had obtained from HHS-OIG earlier that year. Gov't Ex. 26. In May 2012, a Teva employee circulated a PowerPoint presentation prepared by a law firm reiterating that "the independent charity PAP must not function as a conduit for payments form the pharmaceutical manufacturer to patients." Gov't Ex. 28 at 7. And in May 2014, Hensley e-mailed Lynch a copy of the 2014 HHS-OIG bulletin. Gov't Ex. 29.

148. Notably, Hensley stated in his affidavit that after Lynch retired from Teva, she told Hensley that "she had warned Teva's senior leadership years before that Teva should 'take a reserve' to cover False Claims Act liabilities associated with Teva's donations to Chronic Disease Fund and The Assistance Fund 'in the event' that the donations came under government scrutiny." Hensley Aff. ¶ 18.

(vi) Teva's Illegal Kickback Scheme Continued Through at Least 2018

149. Although the DOJ's recent suit addressed conduct occurring between 2006 and 2015, the House Committee found evidence that this conduct continued through at least 2018. House Report at 17. For example, the House Report cited an October 2016 business plan that

[62] HHS-OIG, Advisory Opinion 06-10 at 5, *available at* https://oig.hhs.gov/fraud/docs/advisoryopinions/2006/AdvOpn06-10A.pdf.

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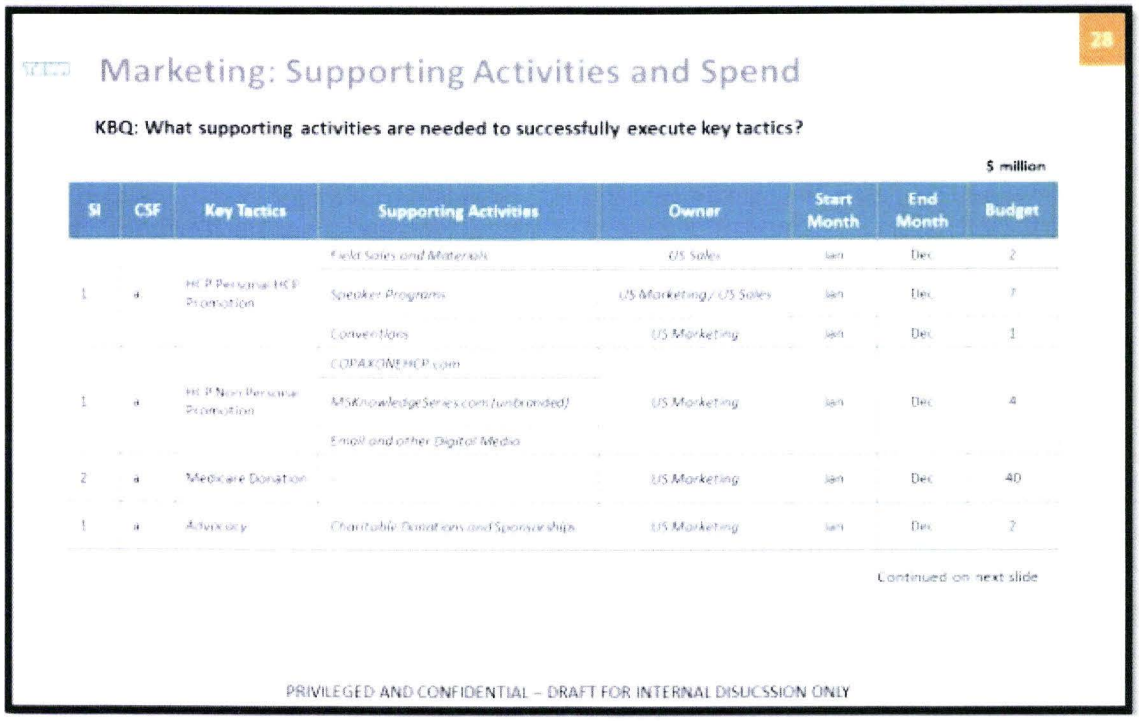
was circulated by Teva executives that listed a $40 million "Medicare donation" as part of its Copaxone "marketing strategy." House Report at 18.



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Marketing: Supporting Activities and Spend

KBQ: What supporting activities are needed to successfully execute key tactics?

$ million

SI	CSF	Key Tactics	Supporting Activities	Owner	Start Month	End Month	Budget
			Field Sales and Materials	US Sales	Jan	Dec	2
1	a	HCP Personal HCP Promotion	Speaker Programs	US Marketing / US Sales	Jan	Dec	7
			Conventions	US Marketing	Jan	Dec	1
			COPAXONEHCP.com				
1	a	HCP Non-Personal Promotion	MSKnowledgeSeries.com (unbranded)	US Marketing	Jan	Dec	4
			Email and other Digital Media				
2	a	Medicare Donation		US Marketing	Jan	Dec	40
1	a	Advocacy	Charitable Donations and Sponsorships	US Marketing	Jan	Dec	2

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150. The House Report also cited a January 17, 2017, email and attachment documenting $38 million in 2017 "Copaxone donations" to TAF, the Patient Access Network Foundation's MS Fund, and HealthWell Foundation's MS Medicare Access Fund. House Report at 13 n.46. Later in 2017, Teva's VP of Finance for North American Specialty Medicine, David Loughery, recommended to North American Specialty Medicine's President that Teva Neuroscience cut other "less impactful" items in its budget to facilitate an additional $5 million payment to Patient Access Network. House Report at 19. Teva Neuroscience made the requested change. *Id.* As the House Report concluded, "[t]his decision indicates that Teva's Vice President for Finance viewed the payment to Patient Access Network Foundation as an 'impactful' business investment." *Id.*

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151. A 2018 draft Teva strategic document noted that eliminating Teva's "Medicare Donation" would result in the elimination of up to $261 million in Copaxone sales. House Report at 19-20. Notably, Loughery subsequently told the General Manager of Teva Neuroscience, John Hassler, to remove the analysis from the document because he was "not comfortable including the sales impact of the reduced donations." House Report at 20. Loughery nonetheless noted that "we believe that reducing the level of donations could mean that a significant number of patients will not be able to remain on Copaxone due to financial constraints." *Id.*

152. At the beginning of 2018, Teva's Executive Vice President for North America, Brendan O'Grady, received a presentation reporting that if Medicare recipients are unable to pay for their cost-sharing obligations, they would "go off therapy, which would result in a negative impact to the brand of $201-280M." House Report at 21. The speaker's notes to the presentation noted that "Donations" were one of Teva's "[h]igh priority projects for execution." *Id.* O'Grady elsewhere commented that "we buy the patients [sic] copay down to zero." House Report at 22.

153. Teva reported to the House Committee that it provided $23,286,429 in "charitable cash contributions in connection with Copaxone" in 2018. House Report at 21.

154. The House Report stated that documents "suggest that Teva's donations continued to be based on the expectation that they ultimately would be delivered to Copaxone patients." House Report at 17.

d. The Medicare Kickback Scheme Inflated the Price of Copaxone Paid by All Health Plan Payors

155. As the preceding paragraphs make clear, Teva understood that if it were exposed to market forces, fewer patients would have been able to afford Copaxone at the excessively inflated prices Teva was charging. This should have checked Teva's excessive pricing and should have forced Teva to reduce prices or risk losing, by its own analyses, a significant volume of sales. Instead of lowering its prices to a level that patients could afford, Teva chose to illegally circumvent these market forces through its earmarked "donations" to subsidize participant cost-

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sharing obligations. This caused Medicare to continue paying for Copaxone prescriptions despite the ever-increasing cost of the drug.

156. Because a single Copaxone list price applies to virtually all Copaxone purchases in the United States, including for Copaxone prescribed to both Medicare recipients and members of private health plans, Teva's illegal Medicare kickback scheme enabled Teva to increase the price paid by *all payors*. Had Teva been exposed to price competition and the price checking function of cost-sharing obligations with respect to the Medicare portion of its business, Teva would have been forced to reduce its single list price in order to avoid losing Medicare sales, and thus private health plan payors would have paid a lower price for their plan members' Copaxone prescriptions.

2. Teva's Anticompetitive, Unfair, and Deceptive Product Hopping Scheme

157. While Teva had effectively eliminated member price exposure as a check on its excessive pricing, Teva still had to contend with state laws that require or otherwise cause pharmacies to substitute lower-cost generics for brand name prescriptions. Teva's patent exclusivity on Copaxone was set to expire in 2015 and Teva knew that because of state laws and price competition among pharmacies, it was likely to rapidly lose sales to generics as soon as generics became available for purchase. Rather than face these standard market forces, Teva chose an anticompetitive, unfair, and deceptive shortcut.

a. Drug Manufacturers Use Product Hopping Schemes to Avoid Generic Substitution Under Drug Substitution Laws

158. Because generics on average cost substantially less than their brand name counterparts, health plans may save considerable costs if patients' prescriptions are promptly converted over to the generic once it's available.

159. In most marketplaces in which products are otherwise identical, price differential alone would cause consumers to select the lower-cost product. However, in the marketplace for prescription drugs in the United States, there is a disconnect between purchase price and product

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selection because the entity paying for product (the health plan payor) is distinct from the person choosing the product (the physician who writes the prescription). Studies repeatedly show physicians are usually unaware of the costs of pharmaceutical products. Even when physicians are aware of the relative cost, they are often insensitive to price differences because they do not bear the costs of the drugs being purchased. And while health plan members are partially sensitive to price by virtue of their cost-sharing obligations (in the absence of interference from coupon programs like those implemented by Teva), members are often unaware when generics exist and may not know to ask their doctor to write a prescription for a generic.

160. Every state has enacted a drug substitution or product selection law designed to fix the disconnect between the doctors who prescribe (but do not pay for) the drugs and the individuals and institutions who pay for (but do not select) the drugs. These laws allow (or in some cases require) pharmacists to substitute generic versions for a prescribed brand name drug. Even where these laws do not require substitution, pharmacists are far more price sensitive than doctors because they make greater margins on generics and compete with other pharmacies on price. Thus, the result of these drug substitution laws is that even if a doctor prescribes the more expensive brand name product, pharmacies will fill the prescription with the generic.

161. These laws permit substitution only if the generic is "A-rated" by the FDA (e.g., AP-rate in the case of injectable drugs like glatiramer acetate). For a generic drug to receive an A-rating, it must be "therapeutically equivalent" to the brand drug. This means the generic and brand drugs must have the same: (i) active ingredient; (ii) form; (iii) dosage; (iv) strength; and (v) safety and efficacy profile.

162. Product hopping is an anticompetitive, unfair, and deceptive practice that exploits these "therapeutically equivalent" rules in an effort to avoid generic substitution and prolong brand name patent exclusivity. Product hopping occurs when a brand drug company with a product nearing the end of its patent exclusivity introduces a modest reformulation of the brand drug before it faces generic substitution. The reformulation alters the form, dosage, or strength of

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the brand drug such that the reformulated version is not "therapeutically equivalent" to the original drug as defined by the FDA. As such, generic versions of the original brand drug cannot be substituted for the reformulated brand drug under drug substitution laws. And because the reformulated version of the drug enjoys a new period of patent exclusivity, there would be no "therapeutically equivalent" generic, and thus no threat of generic substitution, until the end of the patent exclusivity on the reformulated brand drug.

163. Product hopping is particularly problematic where, as here, the brand drug company coerces or otherwise induces patients to convert to the reformulated version of the brand drug before the patent exclusivity on the original brand drug expires. Drug companies like Teva know that if the reformulated version is delayed until after patients are switched over to lower-cost generics under drug substitution laws, patients would be inclined to remain on the lower-cost generics rather than switching again to a higher-cost reformulation of the brand drug. But if the drug company can coerce or otherwise induce patients into switching to a new version of its brand drug while the original brand drug still enjoys patent exclusivity, patients will not have known the benefit of the lower-cost generic and will have begun the reformulated drug before drug substitution laws kick in.

164. As the European Commission explained in its detailed inquiry into the pharmaceutical industry,

> Timing the launch of a follow-on product is crucial for originator companies. If cheaper, generic versions of the first product come on the market before or simultaneously with the switch to the follow-on product, the originator company may incur considerable value losses both in terms of smaller volumes and reduced prices. Therefore, it is of utmost importance for the originator company to bring the follow-on product on the market before the first product effectively loses exclusivity.[63]

[63] Pharmaceutical Sector Inquiry Final Report, European Comm'n, ¶ 1010 (2009), https://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/staff_working_paper_part1.pdf.

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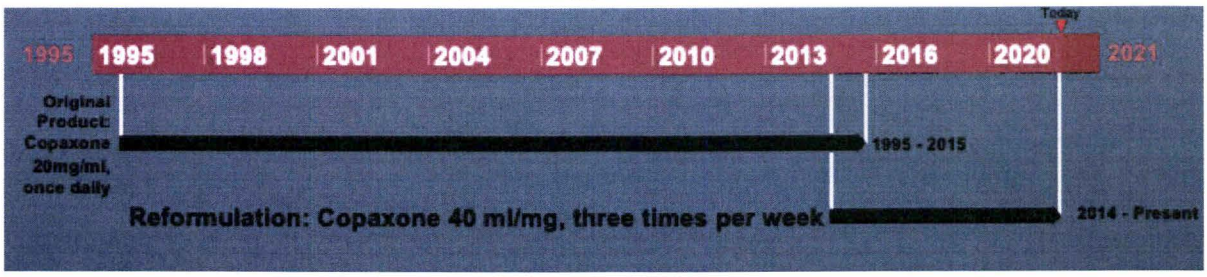
165. It is well known that after doctors have switched patients to the reformulated product, they are unlikely to switch back and prescribe the original product. And because the reformulated drug is not "therapeutically equivalent" to the generic versions of the original brand drug, pharmacists cannot replace prescriptions for the reformulated drug with generic versions of the original drug. As one expert explained, "[i]f the brand successfully switches the market to the reformulated product before the generic enters, the generic entry is of no practical significance: there are few or no prescriptions for the original product for which the generic can be substituted."[64]

b. Teva's Copaxone Product Hop

166. The original version of Copaxone came in a 20mg dosage that was to be taken once daily. Patent exclusivity on 20mg Copaxone was set to expire in 2015.

167. In 2014 Teva introduced a reformulated 40mg version of Copaxone that was to be taken three times weekly. The FDA granted approval for Teva to market the new dose on



January 28, 2014, and Teva released 40mg Copaxone the following day. This was almost 18 months before Sandoz launched Glatopa, the first generic 20mg version of glatiramer acetate.[65]

168. Teva engaged in a multi-pronged campaign to coerce and induce doctors, pharmacies, and patients to switch from 20mg Copaxone to 40mg Copaxone before Glatopa or other 20mg generics became available for purchase.

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[64] Michael A. Carrier, et al., "Product Hopping: A New Framework," 92 Notre Dame L. Rev. 167, 176 (Nov. 2016), https://scholarship.law.nd.edu/ndlr/vol92/iss1/4.

[65] Sandoz, *Press Release: Sandoz Announces U.S. Launch of Glatopa, the First Generic Competitor to Copaxone 20 mg* (June 19, 2015), http://www.us.sandoz.com/news/media-releases/sandoz-announces-us-launch-glatopatm-first-generic-competitor-copaxoner-20mg.

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169. First, Teva manipulated the pricing of both versions of Copaxone to induce patients to switch to 40mg Copaxone. As the House Committee found, Teva initially priced 40mg Copaxone as "slightly less expensive per week of treatment than Copaxone 20mg." House Report at 30. Shortly thereafter, Teva increased the price of 20mg Copaxone by 9.8%. *Id.* The House Committee found that this price increase was "part of Teva's 2014 strategic plan, which emphasized that one method to 'Divert to 40' was to 'raise 20mg price.'" *Id.* In a July 2, 2014 email, Teva's Executive Vice President for North America Brendan O'Grady expressly described how "an important part of our generic defense strategy is creating price separation between 20mg and 40mg."[66] Teva's pricing committee further explained that Teva's objective was to create "rapid transition of COPAXONE 20mg to 40mg prior to expected generics in mid-2014." House Report at 30.

170. Second, Teva pressured PBMs to make 40mg Copaxone available to participants of health plans. Teva threatened PBMs that it would stop paying the PBMs rebates on 20mg Copaxone unless the PBMs made 40mg Copaxone available on their formularies. House Report at 31. On at least one occasion, internal Teva emails indicate that Teva followed through on the threat, eliminating Copaxone rebates for at least one PBM that failed to add 40mg Copaxone to its formulary. *Id.* This pressure worked: the following year, the PBM added 40mg Copaxone to its formulary. *Id.*

171. Third, Teva colluded with PBMs to implement a so-called "Copaxone conversion initiative." Teva entered into contracts with one or more PBMs under which the PBM(s) "committed to converting Copaxone 20mg patients over to Copaxone 40mg with their physician members." House Report at 32. Under this program, the PBM(s) would "contact[] the prescribers

[66] Staff of H.R. Comm. on Oversight and Reform, 116th Cong., Drug Pricing Investigation Teva-Copaxone Selected Investigation Documents (Sept., 2020), https://oversight.house.gov/sites/democrats.oversight.house.gov/files/Document%20Packet%20Teva%209-30-2020.pdf ("Selected Documents").

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via fax and phone to make them aware of which patients are still on Copaxone 20mg and encourage them to switch these patients to Copaxone 40mg." *Id.*

172. Fourth, Teva itself directly targeted physicians with an intense outreach campaign through its sales force. Members of Teva's sales force contacted physicians to tell them to (i) "initiate and upgrade any remaining patients to TIW [three times weekly] Copaxone 40mg"; (ii) "switch patients to TIW Copaxone 40mg if payers force to generic GA for daily dose"; (iii) "Prescribe Copaxone DAW [Dispense as Written] for new and existing patients"; and (iv) "Encourage their patients to accept only branded Copaxone." House Report at 32. And Teva created financial incentives for its sales force to execute this plan, making their bonuses dependent entirely on the sales of 40mg Copaxone. *Id.*

173. Finally, the House Committee found that Teva at least "explored" a plan to coerce patients to switch to 40mg Copaxone by discontinuing copay assistance programs for the 20mg dosage, "which would make it more expensive for patients to remain on the lower dose of the medication." House Report at 30-31. The House uncovered a Teva document describing "Marketing: Deliverables," which indicated that the discontinuation of these "20mg Financial Programs (Patient Services)" was "in process" with a start date of August 14, 2014 and a completion date of December 14, 2014. House Report at 31.

174. These efforts to convert patients from 20mg Copaxone to 40mg Copaxone proved successful. Teva Ltd. CEO Erez Vigodman boasted that by December 2015, Teva converted 76.9% of Copaxone patients to 40mg and limited generic 20mg market share to 19.3%. House Report at 33.

c. Teva's Clear Objective Was to Avoid Generic Substitution

175. Teva's objective was clear. Teva introduced a modest reformulation of Copaxone and pushed its patients to the new version as part of a "generic defense strategy" to avoid generic substitution that otherwise would have occurred under drug substitution laws, thus allowing Teva to continue charging supra-competitive prices for Copaxone without losing sales. An outside

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consultant to Teva characterized the strategy as follows: prior to the launch of the first 20mg generic, Glatopa, "Teva released and promoted a long-acting Copaxone 40MG, effectively pushing existing and new patients to the branded 40MG and minimizing generic substitution." House Report at 34. In June 2016—almost a year after the 20mg generic Glatopa had been on the market—an internal presentation from Teva's General Manager of Neuroscience bragged that "[t]he strategy of switching patients to 40mg version of the medicine is continuing to be successful and reduce the impact of generic competition." House Report at 33-34.

176. Teva's product hop was the result of more than a decade of planning. In 2002, Teva Ltd.'s senior executives began holding meetings on Copaxone "Life Cycle Management" (or "LCM"), which, as the House Committee explained, is "an industry term for the use of incremental research to extend a profitable drug's market monopoly." House Report at 24. These meetings were held at various locations worldwide, including in Boca Raton, Florida, and Berlin, Germany. *Id.* Teva Executives emphasized to Teva Ltd.'s Board of Directors that one objective of life cycle management was to "[m]inimize the risk of generic competition." *Id.*

177. In June 2009, Teva's executives prepared a presentation on "Copaxone LCM—Mid Term Initiatives" for then-CEO of Teva Ltd. Shlomo Yanai. House Report at 27. This presentation described "a need to '[d]evelop a low frequency formulation of GA' to ensure the competitiveness of Copaxone in the future. …'" *Id.* Incredibly, this presentation informed Mr. Yanai that among the "complications" facing Teva in its push to introduce a higher dosage of Copaxone was the fact that there was "'[n]o supporting data for the selected dose or dosing regimen" and that "overall, the data available to date do not support going to higher doses.'" *Id.* at 27-28. The House Report explained that this presentation reported to Mr. Yanai that the product hop strategy "would be more profitable in the United States than in Europe because Teva would get 'no market exclusivity in Europe.'" House Report 28.

178. Internal documents show that Teva originally sought to introduce the new 40mg dose as a "more effective" daily dose to replace the existing 20 mgl/ml daily dose. But Teva's

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internal study (called FORTE) showed there was no difference in efficacy between the two doses. House Report 25-26. Within weeks, Teva executives again briefed Teva Ltd.'s Board of Directors, posing to the Board the question of "how do we justify the higher doses" after FORTE revealed there was no difference in efficacy between the two doses. *Id.* at 26. In other words, the higher dosage was a solution in search of a pretextual problem. Teva's response was to explore "higher doses in [a] less frequent dose regimen." *Id.* at 26.

179. Although Teva has attempted to justify the three-times weekly dosage as more convenient to patients, the House Committee cited a statement from a Teva executive conceding that "every other day over once daily does not represent a significant improvement in convenience." House Report at 25. When Teva nonetheless sought to research a shift to a three-times weekly dosage, one of Teva's scientists in Teva Ltd.'s Innovative Research and Development (IR&D) group expressed that IR&D management were "'strongly against' Teva's study into the less-frequent dosing of Copaxone 'since it has no scientific rationale/value.'" House Report at 27. This scientist further noted that Teva's life cycle management team agrees, but nonetheless they "think that such a study has its business value." *Id.*

180. The House Committee further found that Teva's "[i]nternal discussions in November 2009 undermine Teva's claims that it launched the 40mg three times per week to benefit patients and not to protect the Copaxone franchise." House Report at 28. As the House Report explained:

> That month, Teva decided against doing research on the efficacy of administering Copaxone 40 mg/ml once per week—which presumably would have been even more convenient for patients. Teva [Ltd.]'s then-CEO Shlomo Yanai feared that such research would lead patients to take two injections of a cheaper generic version of Copaxone 20 mg/ml once per week rather than Teva's Copaxone 40 mg/ml.

Id.

181. Another internal Teva document explained that the new dosage would provide Teva with a "Patent protection extension" and would serve as a "Barrier to Generic entrance."

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House Report at 28-29. This document noted that the new dose provided "[n]o major advantage on GA 20mg." *Id.*

182. Despite Teva's true motivations to avoid generic substitution and its internal concessions that 40mg Copaxone was not "a significant improvement in convenience," Teva Ltd.'s press release announcing the FDA approval of 40mg Copaxone misled the public by marketing 40mg Copaxone as "a significant advancement for patients."[67] Moreover, despite Teva's extensive efforts to reverse engineer a justification for altering the dosage of Copaxone, Larry Downey, Teva's President for North America Specialty Medicines, misleadingly stated:

> We have progressively invested in the innovation of COPAXONE® in an effort to understand the needs and to ease the burden of patients who live with relapsing forms of MS every day. Today we are proud to continue to deliver on that investment by offering the freedom to dose three-times-a-week with COPAXONE® 40 mg/mL.[68]

183. Ultimately, Teva's product hopping strategy allowed Teva to effectively avoid generic competition until at least 2017, when generic 40mg glatiramer acetate finally entered the market after Teva's patent on 40mg Copaxone was invalidated by a federal court.

d. Teva's Product Hop Was Extremely Costly

184. Product hopping is extremely costly to the United States healthcare system, as health plans like Plaintiffs continue to pay for higher-cost brand drugs rather than lower-cost generics. And because the reformulated brand drug does not face generic competition, there is no incentive for the brand manufacturer to lower prices. A September 2020 study of just five product hops found that the practice resulted in excess healthcare spending of $4.7 billion annually.

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[67] *Teva Announces U.S. FDA Approval of Three-Times-a-Week COPAXONE® (glatiramer acetate injection) 40mg/mL*, Teva Pharmaceutical Industries, Ltd. (January 29, 2014), https://www.tevapharm.com/news-and-media/latest-news/teva-announces-u.s.-fda-approval-of-three-times-a-week-copaxone-glatiramer-acetate-injection-40mgml/.

[68] *Id.*

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185. The cost of Teva's product hop is no different. A 2020 study by researchers from Harvard University found that by delaying generic competition by two and a half years, Teva's product hop resulted in excess spending by payors in the U.S. health care system of between $4.3 and $6.5 billion.[69] The House Committee reported that "[b]y shifting patients from Copaxone 20 mg/ml to 40 mg/ml, Teva maintained more than $3 billion in annual net revenue from 2015 to 2017." House Report at 35.

3. Additional Anticompetitive Conduct

186. After Mylan introduced a lower priced generic version of Copaxone 40mg in October 2017, Teva pursued several additional anticompetitive tactics to inhibit generic competition and cause payors to continue paying for Copaxone. The House Committee found that "Teva contracted with specialty pharmacies and pharmacy benefit managers to limit generic substitution." House Exec. Summ. at iv. The House Committee also found that "Teva lobbied doctors to write prescriptions for Copaxone that prohibited generic substitution" (i.e. "dispense as written") and "used its patient programs to convince patients to remain on the more expensive brand name version of the drug." *Id.*

a. Teva's "House Brand" Strategy

187. One of the tactics employed by Teva to maintain its market share and high price for Copaxone was a "Brand Over Generic" or so-called "House Brand" contracting strategy. As the name implies, Teva's "Brand Over Generic" strategy involved contracting with PBMs and specialty pharmacies to make Copaxone 40mg the drug that was dispensed to health plan members, as opposed to a cheaper generic version of glatiramer acetate—thereby inverting the usual course under generic substitution laws.

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[69] Benjamin N. Rome, et al., *US Spending Associated with Transition from Daily to 3-Times-Weekly Glatiramer Acetate*, Journal of the American Medical Association Internal Medicine (July 20, 2020), https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2770468.**Error! Hyperlink reference not valid.**

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188. When Mylan received approval to market its generic version of glatiramer acetate, Teva quickly sought to implement its "House Brand" strategy. Documents from the House Report reflect that, on October 26, 2017 (the same month as Mylan's approval), the General Manager of Teva Neuroscience, John Hassler, notified Teva CNS CEO Larry Downey: "'Two weeks post generic approval, the team has already had early success in achieving key Brand Over Generic goals,'" and that "'45% of units have been targeted via House Brand Agreements.'" House Report at 37.

189. With respect to certain PBMs, Teva executed its "House Brand" strategy through contracts that restricted generic access at the formulary level. Internal Teva documents reflected that "2 of the House Brand target accounts will be executed at the formulary level. Blocking the generic via formulary restriction." *Id.*

190. With respect to specialty pharmacies, Teva contracted with certain pharmacies so that prescriptions for glatiramer acetate would be filled with brand, regardless of whether a generic was prescribed. Internal Teva documents reflected that "2 of the House Brand target accounts will be executed at the specialty pharmacy level. Pharmacy will fill brand regardless if prescribed as generic." *Id.*

191. A series of emails uncovered by the House Committee showed how the "House Brand" strategy was effective at preventing health plan members from receiving lower-cost generics. In response to employee questions regarding the effects on Teva should an insurer place 40mg Copaxone on a more restrictive formulary tier, Teva's Executive Vice President for North America, Brendan O'Grady, responded that the insurer's decision would have "almost zero impact on actual prescriptions" because the insurer's members would have their prescriptions filled by a specialty pharmacy that would give members Copaxone instead of the generic:

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On Jan 31, 2018, at 3:51 PM, Brendan O'Grady **Highly Confidential** wrote:

> Because CVS is getting an additional rebate to fill all glatiramer (or Copaxone scripts with Copaxone - if a doctor orders generic glatiramer or the pharmacy benefit mandates it be filled as a generic, it will come in a plain box with Copaxone inside. Win win for all.
>
> Best regards
>
> **Brendan P. O'Grady** EVP and Head of North America

House Report at 37-38. Thus even if a patient wanted the generic, a doctor prescribed the generic, or an insurer sought to favor the generic, Teva's conduct sought to ensure that pharmacies would fill all prescriptions with Copaxone, even if it meant putting Copaxone in a plain box.

192. The House Report further noted: "Earlier in the email, a Teva executive had warned subordinates that the contract with [specialty pharmacy] should 'not be formally shared with the sales team' because of the 'confidential nature of the [specialty pharmacy] House Brand strategy." House Report at 38.

193. The House concluded that "[b]y April 2018, Teva had entered into House Brand Agreements with a number of PBMs for Medicare and commercial patients. Some of these agreements blocked generics from formularies while others replaced generics at the specialty pharmacy." House Report at 39.

b. Dispense As Written

194. Manipulation of physician prescribing decisions plays into another complexity of the pharmacy market, as described by Professor Carrier:

> Unlike other markets, "the consumer who pays does not choose, and the physician who chooses does not pay." This disconnect has created a gap that can be exploited. Brand firms can convince doctors to prescribe expensive drugs even if equally effective cheaper drugs are available. In fact, brands have done so through an array of activity that includes samples, mailing, detailing (sales calls

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> to doctor's offices), sponsored continuing medical education programs, and advertising in medial and medical journals.[70]

195. As described *supra* ¶¶ 160-161, state generic substitution laws allow—or require—pharmacists to fill prescriptions for branded pharmaceuticals with equivalent generic pharmaceuticals. The exception is for prescriptions with the notation "Dispense as Written" or "DAW," by which the prescribing physician can prohibit generic substitution.

196. In response to generic competition, Teva began a campaign to induce doctors to write prescriptions for Copaxone as DAW to stop generic substitution. In internal Teva strategy documents reviewed by the House Committee, the DAW campaign was identified as a key component of Teva's strategy to prevent health plan members from receiving lower-cost generics. Teva told doctors to "'Prescribe Copaxone DAW for new and existing patients.'" House Report at 39. The House Committee also found that Teva executives "touted their '[a]bility to produce current 40mg patient lists for HCP [Health Care Professional] offices' to 'proactively' write DAW on prescriptions." *Id.* at 40.

197. To induce doctors to write Copaxone prescriptions with a DAW notation, Teva misleadingly represented that patients would benefit from remaining on brand Copaxone when, in fact, generic glatiramer acetate contains the same active ingredient as Copaxone and is classified as "therapeutically equivalent" to Copaxone.

198. Mylan Pharmaceuticals Inc., the manufacturer of a generic version of glatiramer acetate, has disclosed that when its own sales representatives visited medical professionals throughout the United States, they learned that many were not prescribing Mylan's generic because they were under the false impression that it "is only 80% as effective as Copaxone" or "is only 85% as effective as Copaxone."[71] Mylan further reported that a "significant portion of

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[70] Michael A. Carrier, *Three Challenges for Pharmaceutical Antitrust*, 59 Santa Clara L. Rev. 615, 616 (2020) (quoting Bureau of Consumer Protection, Drug Product Selection: Staff Report to the F.T.C.2 (Jan. 1979)).

[71] Complaint ¶ 135, *Mylan Pharmaceuticals Inc. v Teva Pharmaceutical Industries Ltd. et al*, No. 21-cv-13087 (D.N.J. June 29, 2021), ECF No. 1.

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the prescribers who have been exposed to the statements attribute them to Teva and sales reps."[72] Statements that generic glatiramer acetate are less effective than Copaxone are false because Mylan's generic is an "A" rated therapeutic equivalent of Copaxone.

199. Mylan also detailed examples of health care professionals who received false or misleading representations from Teva regarding whether Copaxone and generic glatiramer acetate were interchangeable, including a nurse in Central California who said that a Teva representative told her that generic glatiramer acetate was not the same medication as Copaxone and that her patients would suffer from switching, a doctor in San Antonio, Texas who was incorrectly informed that Copaxone was too complicated to be copied by generic manufactures, and a doctor in Southern California who was convinced that generic glatiramer acetate was materially different from Copaxone.[73] Mylan reported that its "sales representatives frequently have encountered such statements from medical professionals throughout the United States."[74]

200. While health care professionals are highly knowledgeable decision-makers, it is reasonable for them to trust that drug manufacturers' statements regarding drugs are supported with evidence and rely on those statements. This is especially true where, as here, those statements extend beyond puffery into seemingly factual descriptions of the composition of the drug. Furthermore, Teva's false statements evaded correction or mitigation from competitors by virtue of the sheltered nature of the communications between Teva representatives and health care professionals via private portals and targeted conversations. These statements were part of Teva's widespread and long-lasting campaign to spread misinformation about generics to manipulate health care professionals so that patients would stay on Copaxone.

[72] *Id.* ¶ 138.
[73] *Id.* ¶¶ 155-158.
[74] *Id.* ¶ 158.

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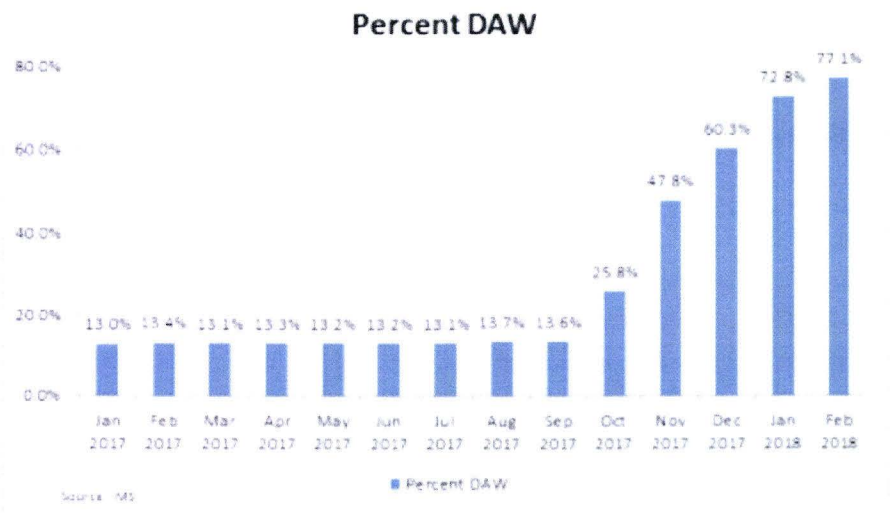
201. Teva's DAW campaign was highly successful. "By February 2018, 77% of Copaxone prescriptions were written with the 'DAW' notation." *Id.*



Id.

202. In August 2018, Brendan O'Grady encouraged his team to "Keep up pressure on Copaxone and maximize office calls," noting that "the DAW campaign combined with the legacy and house brand access strategy has paid great dividends." House Report at 40. O'Grady set a goal of $1.5 billion in net Copaxone revenue for 2018. *Id.* Teva ultimately exceeded this goal, collecting $1.6 billion in net Copaxone revenue for the year despite the availability of lower-costs generics. *Id.* at 41.

203. Teva's conduct did not go unnoticed. In 2019, Teva S&M agreed to settle claims brought by two whistleblowers alleging that Teva's marketing, promotional, and sales practices induced physicians to prescribe two of its drugs, including Copaxone, by paying them as "speakers" or "consultants" in connection with "sham" speaker events where the physicians received fees and expensive meals in return.[75]

[75] Eve Costopoulos, Elizabeth H. Kim, Scott S. Liebman, *Teva Sales and Marketing Inc. Settlement Agreement*, LEXOLOGY (Jun. 7, 2022), https://www.lexology.com/library/detail.aspx?g=78947811-f4d3-4ffd-be98-a3e4d2ecba1b.

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c. Shared Solutions

204. Teva also used its patient assistance program, known as Shared Solutions, to induce patients to remain on the more expensive brand version of the drug.

205. The Shared Solutions program offers a variety of services to Copaxone users, including providing free injection devices, free injection training, and assistance with obtaining insurance coverage.

206. As noted above, Teva was able to quickly enroll patients in Shared Solutions because when Physicians prescribed Copaxone, they would typically submit enrollment forms to Shared Solutions on behalf of each new Copaxone patient. Gov't Compl. ¶ 48.

207. Through this program, Teva told members of private health plans to ask their doctors to write Copaxone prescriptions with the DAW notation, further reinforcing Teva's DAW program and undermining drug substitution laws. Teva misleadingly represented that health plan members would benefit from remaining on brand Copaxone when, in fact, generic glatiramer acetate contains the same active ingredient as Copaxone and is classified as "therapeutically equivalent" to Copaxone. Teva also misleadingly informed patients that their out-of-pocket expenses (after using Teva's coupons) might be as low as $10 per month,[76] in contravention of the requirements of the participants' health plans.

208. Internal Teva documents reflect that through this program, Teva sent "'[e]mails to all patients with DAW messaging.'" House Report. at 23. Another Teva document from August 2018 emphasized the need to "reinforce DAW on every call" and use "Marketing driven patient programs and telecons to supplement patient education/support." *Id.* at 23-24.

209. Teva also pressed the DAW campaign through its "Shared Solutions" program to great success. The House Report noted: "According to an internal analysis in August 2017,

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[76] *See, e.g., Here with Proactive Prescription Tips,* Copaxone, https://www.copaxone.com/injection-assistance/copaxone-generic (last visited Mar. 28, 2021).

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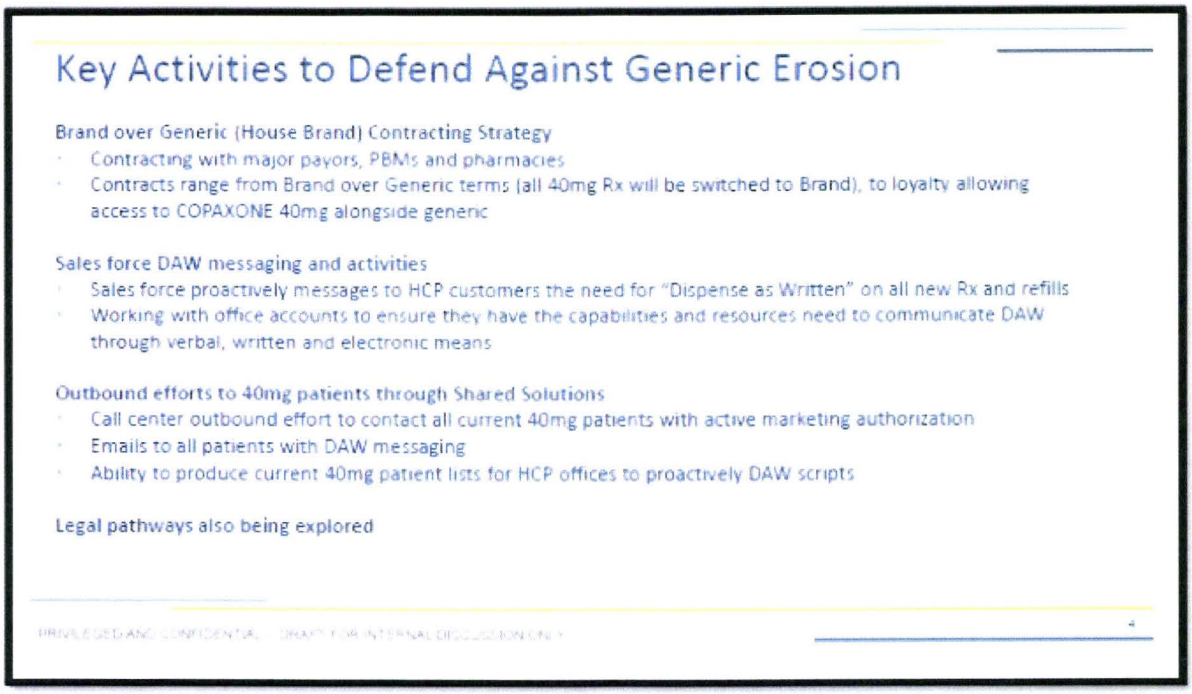
DAW was written on 87% of Copaxone 40mg prescriptions requested through Teva's 'Shared Solutions Copaxone Prescription Service Request form.'" House Report at 39.

* * *

210. Teva Ltd.'s Board of Directors was briefed in October of 2017 regarding Teva's



Key Activities to Defend Against Generic Erosion

Brand over Generic (House Brand) Contracting Strategy
- Contracting with major payors, PBMs and pharmacies
- Contracts range from Brand over Generic terms (all 40mg Rx will be switched to Brand), to loyalty allowing access to COPAXONE 40mg alongside generic

Sales force DAW messaging and activities
- Sales force proactively messages to HCP customers the need for "Dispense as Written" on all new Rx and refills
- Working with office accounts to ensure they have the capabilities and resources need to communicate DAW through verbal, written and electronic means

Outbound efforts to 40mg patients through Shared Solutions
- Call center outbound effort to contact all current 40mg patients with active marketing authorization
- Emails to all patients with DAW messaging
- Ability to produce current 40mg patient lists for HCP offices to proactively DAW scripts

Legal pathways also being explored

"Key Activities to Defend Copaxone Against Generic Erosion." House Report 23. Among other things, Teva Ltd.'s Board received details about Teva's "House Brand" strategy to contract with PBMs and pharmacies and Teva's DAW campaign. *Id.*

V. RELEVANT MARKET AND TEVA'S MARKET POWER

211. The relevant product market is the market for glatiramer acetate, including Copaxone and FDA-approved, AP-rated generic versions of Copaxone.

212. Copaxone is not reasonably interchangeable with other RRMS drugs, except for AP-rated generic versions of Copaxone, because Copaxone is therapeutically distinct.

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213. Unlike many consumer products, for which consumers are provided a choice of functionally similar products at the point of sale and make purchasing decisions based primarily on price, the initial purchasing decision for prescription medications and devices is generally made by doctors, not the products' consumers. Once a prescriber and patient find a product that is well-tolerated, it is unlikely that price variations would cause either to switch to a different MS treatment other than a generic version of the current therapy.

214. The existence of other FDA-approved RRMS disease-modifying treatments has not significantly affected Teva. RRMS is distinctive for the lack of interchangeability between treatments. Although these treatments have the same goal of reducing relapses and forestalling the disease, a patient who is stabilized on and tolerating one form of treatment is unlikely to switch to another type of treatment. For one thing, different RRMS treatments use different forms of administration, which may impact efficacy and patient tolerance: glatiramer acetate is administered through an injection, while other RRMS treatments are oral therapies and infusions. But even with respect to treatments that use the same form of administration, patients are highly unlikely to change once they establish a history of tolerating a particular RRMS treatment. This is because changing MS treatments raises the prospect of considerable, life-altering consequences, including side effects and changes in long-term tolerability, the severity of which may depend on patient-specific factors such as the presence of co-morbidities.

215. In part because of the lack of interchangeability between treatments and the long-lasting nature of the disease, patients remained on glatiramer acetate despite the introduction of other RRMS disease-modifying treatments. Teva continued to increase the price of Copaxone even when new disease-modifying treatments were approved and marketed for sale.

216. Despite the existence of other RRMS disease-modifying treatments, Teva has successfully maintained its profitable prices because only the entry of an AP-rated equivalent generic version of Copaxone into the market would cause a significant loss of Teva's sales, and

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Teva's anticompetitive conduct prevented the entry of those generic equivalents and otherwise restricted competition from those generic equivalents.

217. A small but significant non-transitory increase in the price of Copaxone would not have caused a significant loss of sales to other RRMS disease-modifying treatments with the exception of AP-rated generic glatiramer acetate.

218. The relevant geographic market is the United States and its territories.

219. At all relevant times, Teva had substantial market power in the market for glatiramer acetate because Teva had the power to maintain the price of Copaxone at supra-competitive levels without losing substantial sales to competitors, except for AP-rated generic glatiramer acetate.

220. Direct evidence demonstrates that, but for Teva's anticompetitive conduct, generic versions of glatiramer acetate would have more quickly entered the market at significantly lower prices and health plan payors would have paid for available generic versions instead of more expensive Copaxone.

221. Moreover, even after AP-rated generic versions of glatiramer acetate became available on the market, Teva manipulated decisionmakers and otherwise engaged in anticompetitive conduct to prevent health plans from paying for the lower cost generics despite their availability. This allowed Teva to maintain a significant share of the market despite its price increases.

222. Indirect evidence also establishes Teva's monopoly power and market power. At all relevant times, Teva had, and exercised, the power to exclude and restrict competition in the FDA-approved glatiramer acetate market because it enjoyed high barriers to entry, including patent protection, the cost of developing glatiramer acetate products, the high cost of entry and expansion, and laws governing generic substitution.

223. Teva has sold Copaxone in the United States since 1997, and since 2000 has been aggressively increasing prices annually. As the House Committee report concluded, Teva's costs

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did not justify these price hikes. Teva instead reaped excessive profits from Copaxone, and Teva continues to sell Copaxone in excess of its marginal costs.

224. Teva's anticompetitive conduct has forced health plan payors to pay for Copaxone at artificially high prices while simultaneously ensuring that lower cost generic glatiramer acetate products are unavailable to them.

225. During the relevant time, Teva has been able to profitably maintain the price of Copaxone well above competitive levels.

VI. ANTITRUST INJURY AND HARM TO PLAINTIFFS AND COMPETITION

226. Teva engaged in anticompetitive conduct to wrongfully obtain, maintain, and exert its monopoly in the glatiramer acetate market in the United States. As a result of its wrongful conduct, Teva preserved substantial market power, which it in turn used to charge supracompetitive prices and restrict consumer choice.

227. Teva's anticompetitive scheme unreasonably restrained competition in the glatiramer acetate market by blocking competitive products from entering the market and then artificially restricting their ability to compete once they entered the market, including by manipulating the decision-making of doctors, patients, and pharmacists.

228. And Teva's anticompetitive scheme injured consumers, including health plan payors, by artificially inflating the price of Copaxone and depriving them of access to lower cost generic alternatives. As the House Committee report concluded, Teva's costs did not justify price hikes, yet Teva continued to aggressively raise prices.

229. Inflated Copaxone prices were the direct and foreseeable result of Teva's wrongful anticompetitive conduct. Absent Teva's illegal conduct, Plaintiffs and the other members of the Class would have paid less for FDA-approved glatiramer acetate treatments because they would have paid for lower-cost generic versions of Copaxone or purchased branded Copaxone at a reduced price. Plaintiffs and the class have suffered overcharges, constituting

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substantial damages to their business and property, the exact amount of which will be subject of proof at trial.

VII. EFFECT ON INTERSTATE AND INTRASTATE COMMERCE

230. Teva sold glatiramer acetate across state lines at all relevant times.

231. Contracts, bills, and other forms of business communications pertaining to the payment for and sale of Copaxone were transmitted in a continuous and uninterrupted flow across state lines.

232. Teva employed various methods in furtherance of their efforts to monopolize and restrain competition in the glatiramer acetate market, including the United States mail, interstate and foreign telephone lines, and interstate and foreign travel. Teva's activities were within the flow of and have substantially affected interstate commerce.

233. Teva's anticompetitive conduct occurred in part in trade and commerce within the states set forth herein. Teva's anticompetitive and deceptive conduct had substantial interstate and intrastate effects because it induced physicians within each state into prescribing brand Copaxone instead of lower-priced generic alternatives, caused pharmacies to dispense brand Copaxone instead of generics, and forced health plans and employers within each state to continue paying supra-competitive prices for Copaxone prescriptions. This directly impacted and disrupted commerce for consumers and health plan payors within each state who have been forced to continue paying supra-competitive prices. But for Teva's anticompetitive and deceptive conduct, Plaintiffs and other Class members would have paid less for glatiramer acetate.

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VIII. EQUITABLE TOLLING, DISCOVERY RULE, AND FRAUDULENT CONCEALMENT

234. At all times relevant to this Complaint, Teva took active steps to conceal its unlawful activities, including through the combination or conspiracy alleged herein. For example, and without limitation, Teva and its co-conspirators concealed their efforts to defraud Medicare by funneling sham "donations" through non-profit foundations. By paying pharmacies to not collect cost-sharing obligations from private health plan members through their "co-pay" assistance program and by causing pharmacies to report the full, undiscounted drug price when submitting claims to PBMs and private health plans, Teva and its co-conspirators concealed the extent to which they induced payors to pay for Copaxone. Teva misrepresented why it introduced 40mg Copaxone and otherwise concealed its true motive of avoiding generic substitution, and further concealed its efforts to collude with PBMs and physicians to convert participants to 40mg Copaxone before generic versions of 20mg glatiramer acetate hit the market. Teva also concealed its efforts to conspire with PBMs to make Copaxone the exclusive or prioritized drug on formularies and to conspire with specialty pharmacies to have generic prescriptions filled with Copaxone.

235. **Discovery Rule:** Plaintiffs and the members of the Class had no knowledge of the combination or conspiracy alleged herein, or of facts sufficient to place them on inquiry notice of the claims set forth herein, until August and September of 2020, when the government filed its complaint related to Teva's scheme to defraud Medicare and the House Committee released its report.

236. Plaintiffs and members of the Class payors who did not interact with Teva had no means from which they could have discovered the combination and conspiracy described in this Complaint before August and September of 2020.

237. Information in the public domain was insufficient to place Plaintiffs and members of the Class on inquiry notice of Teva's unlawful, anticompetitive, unfair, and deceptive

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activities, including the combination or conspiracy alleged herein, prior to August and September of 2020. Further, Plaintiffs and the members of the Class had no means of obtaining any facts or information concerning the Teva's unlawful, anticompetitive, unfair, and deceptive activities alleged herein, all of which were purposefully concealed by Defendants.

238. For these reasons, any statutes of limitations applicable to the claims of Plaintiffs and the Class did not begin to run and have been tolled until the Government filed its complaint in August 2020 and the House Committee released its report in September 2020.

239. **Fraudulent Concealment:** The statutes of limitation were further tolled by the doctrine of fraudulent concealment. Teva's anticompetitive agreements with various third-parties were self-concealing and Teva also actively concealed the existence of its illegal scheme, including through false or misleading representations.

240. Teva's anticompetitive conduct and agreements with third parties were self-concealing by nature. Had Teva's conduct, including its illegal payments to Medicare recipients, payments and anticompetitive agreements with pharmacies, or conspiracy with PBMs been disclosed, it would have been subject to liability.

241. Teva did not rely just on the self-concealing nature of its scheme, though. Teva actively concealed its illegal payments to Medicare recipients by funneling them through CDF and TAF. Teva represented that it was making disinterested "donations" to CDF and TAF to help patients afford any and all MS prescriptions when, in fact, it took concerted efforts to ensure that its "donations" would be utilized exclusively for Copaxone patients. Teva concealed the illegal communication of data and information necessarily to calculate the precise amounts of its contributions by using ACS and AssistRx as conduits for information. CDF and TAF likewise held themselves out as bona fide charities providing assistance for all MS prescriptions when, in fact, they were serving as "pass-through donation vehicle[s]" to funnel money from Teva to Copaxone patients. These efforts, in combination with Teva's knowledge that its kickback

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scheme violated the law, demonstrate that Teva intentionally and knowingly sought to conceal its illegal conduct.

242. Teva concealed its efforts to induce payors to pay for Copaxone by paying pharmacies to not collect cost-sharing obligations from private health plan members and by causing pharmacies to report the full, undiscounted drug price when submitting claims to PBMs and private health plans.

243. Teva misrepresented why it introduced 40mg Copaxone and otherwise concealed its true motive of avoiding generic substitution. Teva represented that 40mg Copaxone was more convenient, but internal Teva discussions and documents indicate this was merely a "generic defense strategy" to "minimize[e] generic substitution," that Teva knew the change in dosage "does not represent a significant improvement in convenience," that there was "no supporting data for the selected dose or dosing regimen," that Teva's data "do not support going to higher doses," that Teva's own scientists opposed testing the new dosage because it had "no scientific rationale / value," and that Teva was in search for a pretextual justification for changing dosages. Teva nonetheless engaged in an extensive outreach campaign, with the assistance of PBMs, to mislead patients and doctors so they would transition from 20mg Copaxone to 40mg Copaxone.

244. Teva concealed its efforts to conspire with PBMs and specialty pharmacies to have generic prescriptions filled with Copaxone. Indeed, in a January 2018 email chain, a Teva executive warned subordinates that the contract with [specialty pharmacy] should 'not be formally shared with the sales team' because of the 'confidential nature of the [specialty pharmacy] House Brand strategy." House Report at 38. Internal communications regarding the exclusionary contracts in the same email chain are marked "BACKGROUND USE ONLY. DO NOT COPY. DO NOT DISTRIBUTE." Selected Documents at 60.

245. Teva's fraudulent concealment prevented Plaintiffs and the Class from discovering this conduct.

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246. Plaintiffs exercised appropriate due diligence under the circumstances. Plaintiffs monitored drug prices for significant increases; monitored highly priced brand drugs that had significant member utilization, including Copaxone; and took steps to educate prescribers and members about the availability of lower-cost generic drugs. However, Plaintiffs lacked the ability to discover the mechanisms Teva used to manipulate the decisions of doctors, specialty pharmacies, and health plan members. Because it has no subpoena power (or other mechanism to audit the internal records of international pharmaceutical companies), Plaintiffs could not discover Teva's multiple schemes to stall generic competition and extract enormous profits from its anticompetitive conduct. Thus, Plaintiffs lacked the ability to discover that the drug prices they were paying were *higher than they should have been* because of anticompetitive, fraudulent, or otherwise deceptive conduct.

247. Drug prices can increase for a variety of reasons, and no information available to Plaintiffs alerted them to Teva's fraudulent, anticompetitive, unfair, and deceptive conduct and the effects it had on Copaxone prices or on the number of Copaxone prescriptions health plan members filled. Indeed, it required the investigation—and subpoena power—of the federal government to uncover the facts that led Plaintiffs to bring these claims, further confirming the self-concealing nature of Teva's scheme. Thus, Plaintiffs remained unaware of both their injury and the fraudulent, anticompetitive, unfair, and deceptive conduct alleged herein until the U.S. Government filed its complaint in August 2020 and the House of Representatives released its report in September 2020.

248. **Continuing Tort:** Plaintiffs' claims accrue each time they suffered injury as a result of Teva's conduct. Plaintiffs suffered injury each time it paid prices for Copaxone that were higher than it would have paid for glatiramer acetate absent Teva's anticompetitive conduct. Each sale of brand Copaxone at artificially inflated prices constitutes an overt act in furtherance of Teva's continuing anticompetitive scheme.

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249. Additional overt acts in furtherance of Teva's continuing anticompetitive scheme include, but are not limited to: introducing a product hop from the original 20mg dosage to a 40mg dosage and engaging in conduct to coerce patents to switch to the new dose shortly before the patent on the original 20mg dosage of Copaxone expired; each time Teva provided health plan members with "coupons" that relieved them of some or all of their cost-sharing obligations if they purchased Copaxone; each time Teva contracted with and took steps to implement its contracts with PBMs and specialty pharmacies to induce them to make brand Copaxone the preferred drug on formularies and to fill prescriptions with Copaxone rather than generics; each time Teva and its sales representatives made material misrepresentations as to the efficacy and availability of nursing support for generics; each time Teva took steps to execute its extensive campaign to pressure doctors to write prescriptions with a "dispense as written" notation, which precluded pharmacists from substituting with available generics; and each time Teva filed objectively baseless patent lawsuits and citizen petitions to delay the entry of generic versions of glatiramer acetate.

250. As a result, Teva is estopped from relying on any statute of limitations defense because their illegal, anticompetitive, deceptive, and fraudulent practices as alleged herein, which are continuing, have created continuing and repeated injuries to Plaintiffs and the Class.

IX. CLASS ACTION ALLEGATIONS

A. Class Definitions

251. Pursuant to provisions of the Federal Rules of Civil Procedure ("Rule") 23(a), (b)(2), and (b)(3), Plaintiffs bring this action on behalf of themselves and a proposed national class of other similarly situated entities (collectively, "the Nationwide Class"), defined as follows:

> **Class:** All entities in the United States and its territories that are at risk, pursuant to a contract, policy, or plan, to pay or reimburse all or part of the cost of prescription drugs prescribed to natural persons covered by such contract, policy, or plan ("plan members"), and who paid and/or provided reimbursement for some or all of the

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purchase price for Copaxone[77] prescribed to plan members at any time from 2006 until the effects of Teva's unlawful conduct cease.

Antitrust Subclass: All entities in the Antitrust States[78] that are at risk, pursuant to a contract, policy, or plan, to pay or reimburse all or part of the cost of prescription drugs prescribed to natural persons covered by such contract, policy, or plan ("plan members"), and who paid and/or provided reimbursement for some or all of the purchase price for Copaxone prescribed to plan members at any time from 2006 until the effects of Teva's unlawful conduct cease.

CPA Subclass: All entities in the CPA States[79] that are at risk, pursuant to a contract, policy, or plan, to pay or reimburse all or part of the cost of prescription drugs prescribed to natural persons covered by such contract, policy, or plan ("plan members"), and who paid and/or provided reimbursement for some or all of the purchase price for Copaxone prescribed to plan members at any time from 2006 until the effects of Teva's unlawful conduct cease

252. Excluded from the Class and Subclasses are:

a. Defendants and their subsidiaries, and affiliates;

b. Federal and state governmental entities except for tribes, cities, towns, municipalities, counties, or other units of local government that have self-funded health plans that cover prescription drugs; and

c. Health plans that are fully insured (i.e., plans that purchased insurance from another entity that covered 100% of the plan's reimbursement obligations to its members).

253. Plaintiffs reserve the right to revise the definitions of the Class and Subclass based upon information learned through discovery.

B. Requirements of Rule 23

254. The Class consists of tens of thousands of health plans and other payors throughout the United States. It is therefore so numerous and geographically dispersed that it would be impractical to join all Class Members before the Court.

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[77] As used in the Class and Subclass definitions, "Copaxone" refers to both the 20mg/ml and 40mg/ml doses of Copaxone.

[78] The "Antitrust States" are the states identified in the First, Second, and Third Counts below.

[79] The "CPA States" are the states identified in the Fifth Count below.

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255. There are numerous and substantial questions of law or fact common to all of the members of the Class and which predominate over any individual issues. Included within the common question of law or fact are:

a. Whether Teva engaged in a course of conduct that illegally suppressed generic competition, improperly induced Plaintiffs and the Class to pay for Copaxone, and improperly increased the amounts Plaintiffs and the Class paid for glatiramer acetate;

b. Whether Teva engaged in anticompetitive conduct that violated federal laws as alleged herein;

c. Whether Teva engaged in anticompetitive conduct that violated state antitrust laws as alleged herein;

d. Whether Teva engaged in unfair, deceptive, of other impermissible conduct that violated state consumer protection laws as alleged herein;

e. Whether Plaintiffs and the other members of the Class were injured by Teva's conduct and, if so, the appropriate class-wide measure of damages;

f. Whether Teva was unjustly enriched; and

g. Whether Plaintiffs and the other members of the Classes are entitled to injunctive relief.

256. The claims of the Plaintiffs are typical of the claims of Class Members, in that they share the above-referenced facts and legal claims or questions with Class Members, there is a sufficient relationship between the damage to Plaintiffs and Teva's conduct affecting Class Members, and Plaintiffs have no interests adverse to the interests of other Class Members.

257. Plaintiffs will fairly and adequately protect the interests of Class Members and have retained counsel experienced and competent in the prosecution of complex class actions including complex questions that arise in consumer protection litigation.

258. A class action is superior to other methods for the fair and efficient adjudication of this controversy, since individual joinder of all Class Members is impracticable and no other group method of adjudication of all claims asserted herein is more efficient and manageable for at least the following reasons:

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a. Absent certification of the Class, the Class Members will continue to suffer damage and Teva's unlawful conduct will continue without remedy while Teva profit from and enjoy their ill-gotten gains;

b. Given the size of individual Class Members' claims, few, if any, Class Members could afford to or would seek legal redress individually for the wrongs Teva committed against them, and absent Class Members have no substantial interest in individually controlling the prosecution of individual actions;

c. When the liability of Teva has been adjudicated, claims of all Class Members can be administered efficiently and/or determined uniformly by the Court; and

d. This action presents no difficulty that would impede its management by the Court as a class action, which is the best available means by which Plaintiffs and members of the Class can seek redress for the harm caused to them by Teva.

259. Because Plaintiffs seek relief for the entire Class, the prosecution of separate actions by individual members of the Class would create a risk of inconsistent or varying adjudications with respect to individual members of the Class, which would establish incompatible standards of conduct for Teva.

260. Further, bringing individual claims would overburden the Courts and be an inefficient method of resolving the dispute, which is the center of this litigation. Adjudications with respect to individual members of the Class would, as a practical matter, be dispositive of the interest of other members of the Class who are not parties to the adjudication and may impair or impede their ability to protect their interests. As a consequence, class treatment is a superior method for adjudication of the issues in this case.

X. COMPLIANCE WITH NOTICE REQUIREMENTS

261. Plaintiffs' counsel has provided a copy of this class-action complaint to the Attorneys General of Arizona, Connecticut, Illinois, Nevada, New York, Rhode Island, and Utah, along with a letter to each Attorney General informing them of the filing of this complaint, in accordance with the requirements of: Arizona Revised Statutes § 44-1415(A); Connecticut General Statutes § 35-37; 815 Illinois Compiled Statutes § 505/10a(d); Nevada Revised Statutes

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§ 598A.210(3); New York General Business Law § 340(5); Rhode Island General Laws § 6-36-21; and Utah Code § 76-10-3109.

XI. CLAIMS

FIRST COUNT — VIOLATIONS OF STATE ANTITRUST STATUTES: MONOPOLIZATION
(on behalf of Plaintiffs and the Antitrust Subclass)

262. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

263. At all times relevant, Teva possessed monopoly power in the relevant market and willfully acquired and maintained that power through unlawful means, not as consequence of a superior product, business acumen, or historic accident.

264. Teva possessed substantial market power, constituting monopoly power, in the market for glatiramer acetate. Teva's ability to raise prices of Copaxone above competitive levels without losing business to competitors demonstrated substantial market power. Teva ultimately possessed the power to exclude rivals and harm the competitive process.

265. Teva willfully and unlawfully obtained and maintained monopoly power by way of their overall anticompetitive scheme; Defendants did not obtain or maintain monopoly power by virtue of superior product, business acumen, or historic accident.

266. Defendants knowingly engaged in an anticompetitive scheme designed to: establish and extend Teva's monopoly over the market for glatiramer acetate; inflate the price of Copaxone and maintain Copaxone prices at supra-competitive levels; maintain and increase the sales of Copaxone despite its supra-competitive price; block the entry of competing products and suppress competition from competing products, which would decrease sales of Copaxone or put downward price pressure on Copaxone; and manipulate the prescribing and purchasing decisions

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of doctors and patients to thwart generic competition. The intended and accomplished goal of Teva's scheme was to use restrictive and exclusionary conduct to stifle competition against Copaxone and control and maintain the price of Copaxone.

267. This anticompetitive scheme comprised of exclusionary and predatory behavior, orchestrated and deployed by Defendants, is alleged above and includes:

- **Sham citizen petition and patent filings**: filing objectively baseless citizen petitions and patent lawsuits to delay the entry of generics that would compete with Copaxone.

- **Commercial copay assistance scheme**: providing health plan members with "coupons" that relieved them of some or all of their cost-sharing obligations if they purchased Copaxone, thereby making decisionmaker insensitive to price, interfering with plan cost-sharing arrangements, and inducing purchases of Copaxone despite its increasing price;

- **Implementing a Medicare kick-back scheme**: conspiring with specialty pharmacies, non-profit foundations, and other entities and engaging in a variety of illegal, anticompetitive, unfair, and deceptive acts necessary to maintain the single price of Copaxone market-wide by extending this form of "copay assistance" to the vast majority of health plan members in the United States, including Medicare recipients and members of private health plans;

- **Product hopping as a generic defense strategy**: introducing a new patented 40mg dosage of Copaxone shortly before the patent on the original 20mg dosage of Copaxone expired and using unfair and deceptive means—including the anticompetitive use of copay assistance, increasing the price of the 20mg dosage, eliminating PBM rebates on the 20mg dosage, contracting with PBMs to convert patients to the 40 mg dosage, and employing the Dispense as Written campaign—to coerce and otherwise induce doctors and patients to switch to the new dosage before competing 20mg generics entered the market, thereby eliminating the ability of pharmacists to substitute for the lower cost generics under drug substitution laws;

- **House Brand strategy:** contracting with one or more PBMs and specialty pharmacies to make 40mg Copaxone the drug that was

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dispensed to health plan members, instead of a cheaper generic version of glatiramer acetate, thereby inverting the usual course under generic substitution laws;

- **Collusive conduct:** participating in an unlawful conspiracy by entering into an unlawful agreement with one or more PBMs to restrict generics and favor Copaxone in formularies and with one or more specialty pharmacies to fill prescriptions with Copaxone rather than generics in order to foreclose competition in a substantial share of the glatiramer acetate market[80]; and

- **False statements regarding the nature and/or quality of generic glatiramer acetate**: making material misrepresentations and deploying an extensive campaign to pressure doctors to write prescriptions with a "dispense as written" notation, which precluded pharmacists from substituting with available generics.

268. Teva's wrongful anticompetitive conduct harmed competition and consumers. As payors, Plaintiffs are consumers in the relevant market as purchasers of Copaxone. Teva delayed generics from entering the market, and then once the generics were available, Teva employed anticompetitive tactics to inhibit the ability of generics to fairly compete. But for Teva's anticompetitive conduct and monopolistic scheme, lower-cost generics would have entered the market sooner and would have been able to fairly compete once they did enter the market, meaning that Copaxone would have faced price competition. Had Teva not stifled competition, Plaintiffs and the Class would have paid for lower-priced generics for some or all of their glatiramer acetate needs and they would have paid less for brand-name Copaxone.

269. Plaintiffs have been injured in their business or property by Teva's antitrust violation by being denied benefits of competition, being deprived the opportunity to pay for a lower-priced generic, and by paying higher prices than they would have had Teva not engaged in

[80] Because the three largest PBMs—CVS Caremark, Express Scripts, OptumRx—administer prescription drug benefits for more than 200 million Americans, a conspiracy with any one of them would necessarily foreclose competition from a substantial share of the market.

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anticompetitive conduct. These injuries are the type of harm that state antitrust laws were designed to prevent and are the result of Teva's unlawful conduct.

270. Teva's unlawful conduct was targeted towards and/or occurred within each of the jurisdictions enumerated in paragraph 273 below.

271. Plaintiffs seek attorneys' fees and costs as well as damages and multiple damages as permitted by law for the injuries they suffered as a result of Teva's anticompetitive conduct.

272. There are no non-pretextual, procompetitive justifications for Teva's anticompetitive scheme. Internal documents reveal Teva's conduct was intended to create barriers to generic entrance and otherwise protect Copaxone from generic competition.

273. Teva's conduct violated the following state antitrust laws:

a. Ariz. Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona by members of the Class;

b. Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq., with respect to purchases in California by members of the Class;

c. Conn. Gen. Stat. §§ 35-24, et seq., with respect to purchases in Connecticut by members of the Class;

d. D.C. Code Ann. §§ 28-4501, et seq., with respect to purchases in the District of Columbia by members of the Class;

e. Fla. Stat. § 501.201 et seq., and Mack v. Bristol-Myers Squibb, 673 So. 2d 100, 104 (Fla. App. 1996), with respect to purchases in Florida by members of the Class;

f. 740 Ill. Comp. Stat. 10/1 et seq., with respect to purchases in Illinois by members of the Class;

g. Iowa Code § 553.1, et seq., with respect to purchases in Iowa by members of the Class;

h. Kan. Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas by members of the Class;

i. Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases in Maine by members of the Class;

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j. Md. Code Ann., Com. Law § 11-204(a), et seq., with respect to purchases in Maryland by members of the Class;

k. Mich. Comp. Laws Ann. §§ 445.772, et seq., with respect to purchases in Michigan by members of the Class;

l. Minn. Stat. §§ 325D.49, et seq., with respect to purchases in Minnesota by members of the Class;

m. Miss. Code Ann. § 75-21-1 et seq., with respect to purchases in Mississippi by members of the Class;

n. Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the Class;

o. Nev. Rev. Stat. Ann. §§ 598A, et seq., with respect to purchases in Nevada by members of the Class;

p. N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by members of the Class;

q. N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases in New York by members of the Class;

r. N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by members of the Class;

s. N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the Class;

t. Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the Class;

u. P.R. Laws tit. 10 § 257, et seq., with respect to purchases in Puerto Rico by members of the Class;

v. R.I. Gen. Laws § 6-36-1 et seq., with respect to purchases in Rhode Island by the Class;

w. S.D. Codified Laws Ann. §§ 37-1-3, et seq., with respect to purchases in South Dakota by members of the Class;

x. Utah Code § 76-10-3101 et seq., with respect to purchases in Utah by members of the Class;

y. Vt. Stat. Ann. tit. 9, § 2453, et seq., with respect to purchases in Vermont by members of the Class;

z. W.Va. Code §§ 47-18-1, et seq., with respect to purchases in West Virginia by members of the Class; and

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aa. Wis. Stat. §§ 133.01, et seq., with respect to purchases in Wisconsin by members of the Class, in that the actions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for branded and generic versions of Copaxone at Wisconsin pharmacies.

SECOND COUNT — VIOLATION OF STATE ANTITRUST LAWS: ATTEMPTED MONOPOLIZATION
(on behalf of Plaintiffs and the Antitrust Subclass)

274. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

275. At all times relevant, Teva engaged in anticompetitive conduct with intent to monopolize and had a dangerous probability of achieving monopoly power.

276. Teva knowingly engaged in an anticompetitive scheme designed to: establish and extend Teva's monopoly over the market for glatiramer acetate; inflate the price of Copaxone and maintain Copaxone prices at supra-competitive levels; maintain and increase the sales of Copaxone despite its supra-competitive price; block the entry of competing products and suppress competition from competing products, which would decrease sales of Copaxone or put downward price pressure on Copaxone; and manipulate the prescribing and purchasing decisions of doctors and patients to thwart generic competition. The intended and accomplished goal of Teva's scheme was to use restrictive and exclusionary conduct to stifle competition against Copaxone and control and maintain the price of Copaxone.

277. This anticompetitive scheme comprised of exclusionary and predatory behavior, orchestrated and deployed by Teva, is alleged above and includes:

- **Sham citizen petition and patent filings**: filing objectively baseless citizen petitions and patent lawsuits to delay the entry of generics that would compete with Copaxone.

- **Commercial copay assistance scheme**: providing health plan members with "coupons" that relieved them of some or all of

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their cost-sharing obligations if they purchased Copaxone, thereby making decisionmaker insensitive to price, interfering with plan cost-sharing arrangements, and inducing purchases of Copaxone despite its increasing price;

- **Implementing a Medicare kick-back scheme**: conspiring with specialty pharmacies, non-profit foundations, and other entities and engaging in a variety of illegal, anticompetitive, unfair, and deceptive acts necessary to maintain the single price of Copaxone market-wide by extending this form of "copay assistance" to the vast majority of health plan members in the United States, including Medicare recipients and members of private health plans;

- **Product hopping as a generic defense strategy**: introducing a new patented 40mg dosage of Copaxone shortly before the patent on the original 20mg dosage of Copaxone expired and using unfair and deceptive means—including the anticompetitive use of copay assistance, increasing the price of the 20mg dosage, eliminating PBM rebates on the 20mg dosage, contracting with PBMs to convert patients to 40 mg dosage, and employing the Dispense as Written campaign—to coerce and otherwise induce doctors and patients to switch to the new dosage before competing 20mg generics entered the market, thereby eliminating the ability of pharmacists to substitute for the lower cost generics under drug substitution laws;

- **House Brand strategy:** contracting with PBMs and specialty pharmacies to make 40mg Copaxone the drug that was dispensed to health plan members, instead of a cheaper generic version of glatiramer acetate, thereby inverting the usual course under generic substitution laws;

- **Collusive conduct:** participating in an unlawful conspiracy by entering into an unlawful agreement with one or more PBMs to restrict generics and favor Copaxone in formularies and with one or more specialty pharmacies to fill prescriptions with Copaxone rather than generics in order to foreclose competition in a substantial share of the glatiramer acetate market[81]; and

- **False statements regarding the nature and/or quality of generic glatiramer acetate**: making material misrepresentations and deploying an extensive campaign to pressure doctors to write

[81] Because the three largest PBMs—CVS Caremark, Express Scripts, OptumRx—administer prescription drug benefits for more than 200 million Americans, a conspiracy with any one of them would necessarily foreclose competition from a substantial share of the market.

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prescriptions with a "dispense as written" notation, which precluded pharmacists from substituting with available generics.

278. Teva intended to monopolize the market for glatiramer acetate by employing this scheme, causing Plaintiffs to pay artificially inflated prices for glatiramer acetate.

279. At all times, there existed a dangerous probability of Teva achieving monopoly power. There existed a dangerous probability that Teva would attain substantial market power and succeed in lessening or destroying competition in the glatiramer acetate market.

280. Plaintiffs have been injured in their business or property by Teva's antitrust violation by being denied benefits of competition, being deprived the opportunity to pay for a lower-priced generic, and by paying higher prices than they would have had Teva not engaged in anticompetitive conduct. These injuries are the type of harm that state antitrust laws were designed to prevent and are the result of Teva's unlawful conduct.

281. Teva's unlawful conduct was targeted towards and/or occurred within each of the jurisdictions enumerated in paragraph 283 below.

282. Plaintiffs seek attorneys' fees and costs as well as damages and multiple damages as permitted by law for the injuries they suffered as a result of Teva's anticompetitive conduct.

283. Teva intentionally and wrongfully attempted to monopolize the market for glatiramer acetate in violation of the following state antitrust laws:

a. Ariz. Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona by members of the Class;

b. Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq., with respect to purchases in California by members of the Class;

c. Conn. Gen. Stat. §§ 35-24, et seq., with respect to purchases in Connecticut by members of the Class;

d. D.C. Code Ann. §§ 28-4501, et seq., with respect to purchases in the District of Columbia by members of the Class;

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e. Fla. Stat. § 501.201 et seq., and Mack v. Bristol-Myers Squibb, 673 So. 2d 100, 104 (Fla. App. 1996), with respect to purchases in Florida by members of the Class;

f. 740 Ill. Comp. Stat. 10/1 et seq., with respect to purchases in Illinois by members of the Class;

g. Iowa Code § 553.1, et seq., with respect to purchases in Iowa by members of the Class;

h. Kan. Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas by members of the Class;

i. Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases in Maine by members of the Class;

j. Md. Code Ann., Com. Law § 11-204(a), et seq., with respect to purchases in Maryland by members of the Class;

k. Mich. Comp. Laws Ann. §§ 445.772, et seq., with respect to purchases in Michigan by members of the Class;

l. Minn. Stat. §§ 325D.49, et seq., with respect to purchases in Minnesota by members of the Class;

m. Miss. Code Ann. § 75-21-1 et seq., with respect to purchases in Mississippi by members of the Class;

n. Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the Class;

o. Nev. Rev. Stat. Ann. §§ 598A, et seq., with respect to purchases in Nevada by members of the Class;

p. N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by members of the Class;

q. N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases in New York by members of the Class;

r. N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by members of the Class;

s. N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the Class;

t. Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the Class;

u. P.R. Laws tit. 10 § 257, et seq., with respect to purchases in Puerto Rico by members of the Class;

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v. R.I. Gen. Laws § 6-36-1 et seq., with respect to purchases in Rhode Island by the Class;

w. S.D. Codified Laws Ann. §§ 37-1-3, et seq., with respect to purchases in South Dakota by members of the Class;

x. Utah Code § 76-10-3101 et seq., with respect to purchases in Utah by members of the Class;

y. Vt. Stat. Ann. tit. 9, § 2453, et seq., with respect to purchases in Vermont by members of the Class;

z. W.Va. Code §§ 47-18-1, et seq., with respect to purchases in West Virginia by members of the Class; and

aa. Wis. Stat. §§ 133.01, et seq., with respect to purchases in Wisconsin by members of the Class, in that the actions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for branded and generic versions of Copaxone at Wisconsin pharmacies.

THIRD COUNT — VIOLATION OF STATE ANTITRUST STATUTES: CONTRACT, COMBINATION, OR CONSPIRACY TO RESTRAIN TRADE
(on behalf of Plaintiffs and the Antitrust Subclass)

284. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

285. At all times relevant, Teva engaged in a conspiracy, the purpose and effect of which was an anticompetitive scheme to increase the sales and price of Copaxone, manipulate doctors' and patients' prescribing and purchasing decisions, and induce Plaintiffs to pay for Copaxone at an inflated price in lieu of lower-cost generics. This scheme was an unreasonable restraint of trade or commerce that ultimately injured competition and Plaintiffs.

286. Teva participated in an unlawful and anticompetitive conspiracy with Advanced Care, Assist Rx, Chronic Disease Fund, and The Assistance Fund to stifle competition by subsidizing cost-sharing payments to induce Medicare plans to pay for Copaxone rather than lower-cost generics. ACS, Assist Rx, Chronic Disease Fund, and The Assistance Fund provided Teva with information so it could calculate donations in the specific amounts necessary to

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subsidize co-pays for Copaxone patients. Chronic Disease Fund and The Assistance Fund used the donations to fund copay assistance for Copaxone rather than lower-priced generics, evading the price-checking function of cost-sharing obligations, inducing Medicare plans to pay for Copaxone, and stifling competition.

287. Teva participated in an unlawful and anticompetitive conspiracy with certain pharmacies and certain specialty pharmacies to undermine the price-checking function of private health plans' cost-sharing obligations to stifle competition by inducing health plan payors to pay for Copaxone rather than lower-cost generics. Teva and certain pharmacies and specialty pharmacies coordinated the use of coupon cards to forgo cost-sharing payments, providing pharmacies and specialty pharmacies a discount on the price of Copaxone while skirting price-checking mechanisms to induce health plan payors to pay for Copaxone rather than lower-cost generics. Teva also contracted with certain specialty pharmacies to have them fill generic glatiramer acetate prescriptions with Copaxone instead.

288. Teva participated in an unlawful and anticompetitive conspiracy with one or more PBMs to induce health plans to pay for Copaxone rather than lower-cost generics. Teva conspired with one or more PBMs to manipulate patients and physicians to switch to a sham reformulation of Copaxone before generic versions became available. This prevented pharmacists from filling prescriptions with lower-cost generics, stifling competition. Teva also contracted with one or more PBMs, paying rebates and other fees as consideration, to ensure that Copaxone was the only version of glatiramer acetate included in the PBMs' formularies. Because the three largest PBMs—CVS Caremark, Express Scripts, OptumRx—control 80% of the prescription drug market and administer prescription drug benefits for roughly 2/3 of all insured

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Americans, a conspiracy with any one of them would necessarily foreclose competition from a substantial share of the market.

289. The probable effect of these agreements was to foreclose competition in a substantial share of the glatiramer acetate market.

290. The foreclosure of competition by restriction of generics and favoring of Copaxone was an unreasonable restraint of trade in the glatiramer acetate market in the United States.

291. Plaintiffs have been injured by Teva's antitrust violation by being denied benefits of competition, being deprived the opportunity to pay for a lower-priced generic, and by paying higher prices than they would have had Defendants not engaged in anticompetitive conduct. These injuries are the type of harm that state antitrust laws were designed to prevent and are the result of Teva's unlawful conduct.

292. Teva's unlawful conduct was targeted towards and/or occurred within each of the jurisdictions enumerated in paragraph 293 below.

293. Teva's conduct violated the following state antitrust laws:

a. Ariz. Rev. Stat. §§ 44-1401, et seq., with respect to purchases in Arizona by members of the Class;

b. Cal. Bus. Code §§ 16700, et seq., and Cal. Bus. Code §§ 17200, et seq., with respect to purchases in California by members of the Class;

c. Conn. Gen. Stat. §§ 35-24, et seq., with respect to purchases in Connecticut by members of the Class;

d. D.C. Code Ann. §§ 28-4501, et seq., with respect to purchases in the District of Columbia by members of the Class;

e. Fla. Stat. § 501.201 et seq., and Mack v. Bristol-Myers Squibb, 673 So. 2d 100, 104 (Fla. App. 1996), with respects to purchases in Florida by members of the Class;

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f. 740 Ill. Comp. Stat. 10/1 et seq., with respect to purchases in Illinois by members of the Class;

g. Iowa Code § 553.1, et seq., with respect to purchases in Iowa by members of the Class;

h. Kan. Stat. Ann. § 50-101, et seq., with respect to purchases in Kansas by members of the Class;

i. Me. Rev. Stat. Ann. 10, §§ 1101, et seq., with respect to purchases in Maine by members of the Class;

j. Md. Code Ann., Com. Law § 11-204(a), et seq., with respect to purchases in Maryland by members of the Class;

k. Mich. Comp. Laws Ann. §§ 445.772, et seq., with respect to purchases in Michigan by members of the Class;

l. Minn. Stat. §§ 325D.49, et seq., with respect to purchases in Minnesota by members of the Class;

m. Miss. Code Ann. § 75-21-1 et seq., with respect to purchases in Mississippi by members of the Class;

n. Neb. Code Ann. §§ 59-801, et seq., with respect to purchases in Nebraska by members of the Class;

o. Nev. Rev. Stat. Ann. §§ 598A, et seq., with respect to purchases in Nevada by members of the Class;

p. N.M. Stat. Ann. §§ 57-1-1, et seq., with respect to purchases in New Mexico by members of the Class;

q. N.Y. Gen. Bus. Law §§ 340, et seq., with respect to purchases in New York by members of the Class;

r. N.C. Gen. Stat. §§ 75-1, et seq., with respect to purchases in North Carolina by members of the Class;

s. N.D. Cent. Code §§ 51-08.1-01, et seq., with respect to purchases in North Dakota by members of the Class;

t. Or. Rev. Stat. §§ 646.705, et seq., with respect to purchases in Oregon by members of the Class;

u. P.R. Laws tit. 10 § 257, et seq., with respect to purchases in Puerto Rico by members of the Class;

v. R.I. Gen. Laws § 6-36-1 et seq., with respect to purchases in Rhode Island by the Class;

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w. S.D. Codified Laws Ann. §§ 37-1-3, et seq., with respect to purchases in South Dakota by members of the Class;

x. Tenn.Code. § 47–25–101, et seq., with respect to purchases in Tennessee by members of the Class;

y. Utah Code § 76-10-3101 et seq., with respect to purchases in Utah by members of the Class;

z. Vt. Stat. Ann. tit. 9, § 2453, et seq., with respect to purchases in Vermont by members of the Class;

aa. W.Va. Code §§ 47-18-1, et seq., with respect to purchases in West Virginia by members of the Class; and

bb. Wis. Stat. §§ 133.01, et seq., with respect to purchases in Wisconsin by members of the Class, in that the actions alleged herein substantially affected the people of Wisconsin, with thousands of end-payors in Wisconsin paying substantially higher prices for branded and generic versions of Copaxone at Wisconsin pharmacies.

FOURTH COUNT — VIOLATION OF THE SHERMAN ACT, 15 U.S.C. § § 1 OR 2 - DECLARATORY AND INJUNCTIVE RELIEF
(on behalf of Plaintiffs and the Class)

294. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

295. For the reasons set forth in the above Counts, Defendants have violated §§ 1 and 2 of the Sherman Act, 15. U.S.C. §§ 1 & 2.

296. Plaintiffs and the Class seek equitable and injunctive relief pursuant to § 16 of the Clayton Act (15 U.S.C. § 26), and other applicable law, to correct for the anticompetitive market effects caused by Teva's unlawful conduct, and other relief as appropriate to prevent similar anticompetitive conduct from reoccurring in the future.

FIFTH COUNT — VIOLATIONS OF THE STATE CONSUMER PROTECTION ACTS
(on behalf of Plaintiffs and the CPA Subclass)

297. Plaintiffs repeat and re-allege each and every allegation set forth above as if fully set forth herein.

298. Plaintiffs bring this action on behalf of themselves and the Members of the CPA Subclass.

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A. Vermont

299. Plaintiffs and the Vermont Members of the CPA Subclass are "consumers" within the meaning of Vt. Stat. Ann. tit. 9, § 2451a(1). Plaintiffs paid consideration for Copaxone in connection with the operation of its business and not for resale in the ordinary course of its business.

300. Defendants are engaged in "commerce" within the meaning of Vt. Stat. Ann. tit. 9, § 2453(a).

301. The Vermont Consumer Protection Act ("Vermont CPA") makes unlawful "unfair or deceptive acts or practices in commerce." Vt. Stat. Ann. tit. 9, § 2453(a).

302. Defendants engaged in unfair and deceptive acts and practices in violation of the Vermont CPA in an elaborate, multi-faceted scheme to increase the sales of Copaxone, inflate the price of Copaxone, manipulate the prescribing and purchasing decisions of doctors and patients, and induce Plaintiffs and the Subclass to pay for Copaxone at an inflated price instead of paying for lower-cost generics.

303. As set forth in more detail above in the factual allegations, examples of Teva's unfair and deceptive acts and practices that violate Vt. Stat. Ann. tit. 9, § 2453(a) include but are not limited to:

a. Defrauding Medicare by illegally funneling kickback payments to Medicare recipients through non-profits in order to induce False Claims against Medicare, thus isolating Teva from the price checks that would have been imposed by cost-sharing obligations and allowing Teva to increase and maintain the high list price of Copaxone for all sales, including to members of private health plans;

b. Causing ACS to certify false claims and PDEs with respect to Medicare claims induced by illegal kickbacks;

c. Using copay coupons to unfairly influence the purchasing decisions of private health plan members and induce private health plan payors, including Plaintiffs and the Subclass, to pay excessive amounts for Copaxone instead of paying for lower-cost generics;

d. Introducing a sham reformulation of Copaxone for the purpose of side-stepping drug substitution laws, thus inducing health plan payors to continue paying for high priced Copaxone instead of lower-cost generic forms of glatiramer acetate;

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e. Misrepresenting the reasons for the introduction of 40mg Copaxone and engaging in an extensive outreach campaign through Teva's sales force to mislead patients and doctors so they would transition from 20mg Copaxone to 40mg Copaxone;

f. Concealing that: the product hop was part of a "generic defense strategy" to "minimize[e] generic substitution"; that Teva knew the change in dosage "does not represent a significant improvement in convenience"; that there was "no supporting data for the selected dose or dosing regimen"; that Teva's data "do not support going to higher doses"; that Teva's own scientists opposed testing the new dosage because it had "no scientific rationale / value"; and that Teva was in search for a pretextual justification for changing dosages;

g. Contracting with one or more PBMs who committed to relay these misrepresentations to physicians to get them to convert patients from 20mg to 40mg Copaxone before the generic 20mg generics hit the market;

h. Contracting with one or more PBMs and paying them rebates and other fees as consideration for their agreement to make Copaxone the exclusive or preferred version of glatiramer acetate that would be included on the PBMs' formularies, thus manipulating the choices available to patients and doctors and inducing payors to pay excessive amounts for Copaxone instead of paying for lower-cost generics;

i. Contracting with certain specialty pharmacies and, on information and belief, providing certain specialty pharmacies with consideration in exchange for their agreement to fill generic glatiramer acetate prescriptions with Copaxone, circumventing the will of patients, the intent of doctors, and the design of health plans that favored generics over brand drugs;

j. Sending misleading messaging to patients and doctors regarding the need for doctors to write Copaxone prescriptions with the notation "Dispense as Written," including by informing patients that their out-of-pocket expenses (after using Teva's coupons) might be as low as $10 per month, in contravention of the requirements of the participants' health plans;

k. Concealing from the public Teva's unfair and deceptive practices which led to and permitted its Copaxone price increases and its inducement of payments from payors;

l. Misrepresenting and/or concealing from the public the true nature of the relationships between Defendants and ACS, AssistRx, TAF, CDF, PBMs, specialty pharmacies, and doctors and the effect of those relationships on the pricing of Copaxone; and

m. Failing to disclose and/or concealing from the public the true purpose of Teva's Copaxone-related patents, patent lawsuits, and citizens' petitions described herein.

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304. Plaintiffs and the Vermont Members of the CPA Subclass were damaged and injured by Defendants' false and/or fraudulent representations and by Defendants' conduct that violates Vt. Stat. Ann. tit. 9, § 2453(a).

305. Plaintiffs and the Vermont Members of the CPA Subclass were damaged and injured by Defendants' illegal Medicare kickback scheme, which allowed Defendants to maintain their market share while charging artificially high prices for Copaxone for all payors, including private payors like Plaintiffs.

306. Teva's unfair and deceptive acts or practices, omissions, and misrepresentations were material to Plaintiffs and the Subclass, and were likely to and/or did deceive Plaintiffs and the Subclass, as well as patients and doctors, and further manipulated the prescribing and purchasing decisions of doctors and patients in order to unfairly induce Plaintiffs and the Subclass to pay for Copaxone at an inflated price instead of paying for lower-cost generics. Plaintiffs and the Subclass interpreted Teva's unfair and deceptive acts or practices, omissions, and misrepresentations reasonably under the circumstances.

307. Plaintiffs and the Subclass, as well as the members of the private health plans for which Plaintiffs and the Subclass pay claims, relied upon Teva's material misrepresentations and omissions regarding Copaxone, as set forth above. These material misrepresentations and other unfair and deceptive practices by Defendants proximately caused Plaintiffs and the Subclass to pay for Copaxone instead of lower-cost generics and to overpay for Copaxone.

308. Plaintiffs and the Subclass suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Teva's unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for Copaxone and the difference between the prices paid for Copaxone and the prices they would have paid for lower-cost generics.

309. Pursuant to Vt. Stat. Ann. tit. 9, § 2461 Plaintiffs and the Subclass seek damages, punitive damages, and attorneys' fees, costs, and any other just and proper relief available under

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the Vermont CPA. Because Teva's actions were fraudulent, including its scheme to defraud Medicare in order to maintain market share while charging inflated prices for Copaxone, Plaintiffs' damages should be trebled.

B. New Hampshire

310. Plaintiffs and the New Hampshire Members of the CPA Subclass are "persons" within the meaning of N.H. Rev. Stat. § 358-A:10 and N.H. Rev. Stat. § 358-A:1(I).

311. Defendants are engaged in "trade and commerce" within the meaning of N.H. Rev. Stat. § 358-A:2 and N.H. Rev. Stat. § 358-A:1(II).

312. The New Hampshire Consumer Protection Act ("New Hampshire CPA") makes unlawful "any unfair or deceptive act or practice in the conduct of any trade or commerce." N.H. Rev. Stat. Ann. § 358-A:2. The New Hampshire CPA is construed to proscribe conduct that attains a level of rascality that would raise an eyebrow of someone inured to the rough and tumble of the world of commerce.

313. Defendants engaged in unfair and deceptive acts and practices in violation of the New Hampshire CPA in an elaborate, multi-faceted scheme to increase the sales of Copaxone, inflate the price of Copaxone, manipulate the prescribing and purchasing decisions of doctors and patients, and induce Plaintiffs and the Subclass to pay for Copaxone at an inflated price instead of paying for lower-cost generics.

314. As set forth in more detail above in the factual allegations, examples of Teva's unfair and deceptive acts and practices that satisfy the "rascality" standard and violate N.H. Rev. Stat. Ann. § 358-A:2 include but are not limited to:

a. Defrauding Medicare by illegally funneling kickback payments to Medicare recipients through non-profits in order to induce False Claims against Medicare, thus isolating Teva from the price checks that would have been imposed by cost-sharing obligations and allowing Teva to increase and maintain the high list price of Copaxone for all sales, including to members of private health plans;

b. Causing ACS to certify false claims and PDEs with respect to Medicare claims induced by illegal kickbacks;

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c. Using copay coupons to unfairly influence the purchasing decisions of private health plan members and induce private health plan payors, including Plaintiffs and the Subclass, to pay excessive amounts for Copaxone instead of paying for lower-cost generics;

d. Introducing a sham reformulation of Copaxone for the purpose of side-stepping drug substitution laws, thus inducing health plan payors to continue paying for high priced Copaxone instead of lower-cost generic forms of glatiramer acetate;

e. Misrepresenting the reasons for the introduction of 40mg Copaxone and engaging in an extensive outreach campaign through Teva's sales force to mislead patients and doctors so they would transition from 20mg Copaxone to 40mg Copaxone;

f. Concealing that: the product hop was part of a "generic defense strategy" to "minimize[e] generic substitution"; that Teva knew the change in dosage "does not represent a significant improvement in convenience"; that there was "no supporting data for the selected dose or dosing regimen"; that Teva's data "do not support going to higher doses"; that Teva's own scientists opposed testing the new dosage because it had "no scientific rationale / value"; and that Teva was in search for a pretextual justification for changing dosages;

g. Contracting with one or more PBMs who committed to relay these misrepresentations to physicians to get them to convert patients from 20mg to 40mg Copaxone before the generic 20mg generics hit the market;

h. Contracting with one or more PBMs and paying them rebates and other fees as consideration for their agreement to make Copaxone the exclusive or preferred version of glatiramer acetate that would be included on the PBMs' formularies, thus manipulating the choices available to patients and doctors and inducing payors to pay excessive amounts for Copaxone instead of paying for lower-cost generics;

i. Contracting with certain specialty pharmacies and, on information and belief, providing certain specialty pharmacies with consideration in exchange for their agreement to fill generic glatiramer acetate prescriptions with Copaxone, circumventing the will of patients, the intent of doctors, and the design of health plans that favored generics over brand drugs;

j. Sending misleading messaging to patients and doctors regarding the need for doctors to write Copaxone prescriptions with the notation "Dispense as Written," including by informing patients that their out-of-pocket expenses (after using Teva's coupons) might be as low as $10 per month, in contravention of the requirements of the participants' health plans;

k. Concealing from the public Teva's unfair and deceptive practices which led to and permitted its Copaxone price increases and its inducement of payments from payors;

l. Misrepresenting and/or concealing from the public the true nature of the relationships between Defendants and ACS, AssistRx, TAF, CDF, PBMs,

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specialty pharmacies, and doctors and the effect of those relationships on the pricing of Copaxone; and

m. Failing to disclose and/or concealing from the public the true purpose of Teva's Copaxone-related patents, patent lawsuits, and citizens' petitions described herein.

315. Plaintiffs and New Hampshire Members of the CPA Subclass were damaged and injured by Defendants' false and/or fraudulent representations and by Defendants' conduct that violates N.H. Rev. Stat. Ann. § 358-A:2.

316. Defendants knew or should have known that their conduct was in violation of the New Hampshire CPA. Defendants' violations of N.H. Rev. Stat. Ann. § 358-A:2 were knowing and/or willful.

317. Plaintiffs and the Subclass were damaged and injured by Defendants' illegal Medicare kickback scheme, which allowed Defendants to maintain their market share while charging artificially high prices for Copaxone for all payors, including private payors like Plaintiffs.

318. Teva's unfair and deceptive acts or practices, omissions, and misrepresentations were material to Plaintiffs and the Subclass, and were likely to and/or did deceive Plaintiffs and the Subclass, as well as patients and doctors, and further manipulated the prescribing and purchasing decisions of doctors and patients in order to unfairly induce Plaintiffs and the Subclass to pay for Copaxone at an inflated price instead of paying for lower-cost generics.

319. Plaintiffs and the Subclass, as well as the members of the private health plans for which Plaintiffs and the Subclass pay claims, relied upon Teva's material misrepresentations and omissions regarding Copaxone, as set forth above. These material misrepresentations and other unfair and deceptive practices by Defendants proximately caused Plaintiffs and the Subclass to pay for Copaxone instead of lower-cost generics and to overpay for Copaxone.

320. Plaintiffs and the Subclass suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Teva's unfair and deceptive practices and omissions

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and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for Copaxone and the difference between the prices paid for Copaxone and the prices they would have paid for lower-cost generics. Teva's violations also present a continuing risk to Plaintiffs and other payors in New Hampshire, who provide health coverage for thousands of patients afflicted by MS. Teva's violations further present a continuing risk to the general public, who in many cases are unable to afford or gain access to affordable treatment for MS. As such, Teva's unlawful acts and practices complained of herein affect the public interest.

321. Pursuant to N.H. Rev. Stat. § 358-A:10, Plaintiffs and the Subclass seek an order enjoining Teva's unfair and/or deceptive acts and practices, damages, double or triple damages, and attorneys' fees, costs, and any other just and proper relief available under the New Hampshire CPA. Because Teva's actions were knowing and/or willful, including its scheme to defraud Medicare in order to maintain market share while charging inflated prices for Copaxone, Plaintiffs' damages should be trebled.

C. New York

322. Plaintiffs and the New York Members of the CPA Subclass are "persons" within the meaning of N.Y. Gen. Bus. Law § 349(h).

323. Defendants are engaged in "business, trade or commerce" within the meaning of N.Y. Gen. Bus. Law § 349.

324. New York's General Business Law prohibits "[d]eceptive acts or practices in the conduct of any business, trade or commerce." N.Y. Gen. Bus. Law § 349(a), (g); N.Y. Gen. Bus. Law § 350 (prohibiting false advertising) ("New York GBL").

325. Defendants engaged in deceptive acts and practices in violation of the New York GBL in an elaborate, multi-faceted scheme to increase the sales of Copaxone, inflate the price of Copaxone, manipulate the prescribing and purchasing decisions of doctors and patients, and induce Plaintiffs and the Subclass to pay for Copaxone at an inflated price instead of paying for

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lower-cost generics. These acts and practices were consumer-oriented in that they exerted an impact broadly on purchasers of prescription drugs.

326. As set forth in more detail above in the factual allegations, examples of Teva's deceptive acts and practices that violate the New York GBL include but are not limited to:

a. Defrauding Medicare by illegally funneling kickback payments to Medicare recipients through non-profits in order to induce False Claims against Medicare, thus isolating Teva from the price checks that would have been imposed by cost-sharing obligations and allowing Teva to increase and maintain the high list price of Copaxone for all sales, including to members of private health plans;

b. Causing ACS to certify false claims and PDEs with respect to Medicare claims induced by illegal kickbacks;

c. Using copay coupons to unfairly influence the purchasing decisions of private health plan members and induce private health plan payors, including Plaintiffs and the Subclass, to pay excessive amounts for Copaxone instead of paying for lower-cost generics;

d. Introducing a sham reformulation of Copaxone for the purpose of side-stepping drug substitution laws, thus inducing health plan payors to continue paying for high priced Copaxone instead of lower-cost generic forms of glatiramer acetate;

e. Misrepresenting the reasons for the introduction of 40mg Copaxone and engaging in an extensive outreach campaign through Teva's sales force to mislead patients and doctors so they would transition from 20mg Copaxone to 40mg Copaxone;

f. Concealing that: the product hop was part of a "generic defense strategy" to "minimize[e] generic substitution"; that Teva knew the change in dosage "does not represent a significant improvement in convenience"; that there was "no supporting data for the selected dose or dosing regimen"; that Teva's data "do not support going to higher doses"; that Teva's own scientists opposed testing the new dosage because it had "no scientific rationale / value"; and that Teva was in search for a pretextual justification for changing dosages;

g. Contracting with one or more PBMs who committed to relay these misrepresentations to physicians to get them to convert patients from 20mg to 40mg Copaxone before the generic 20mg generics hit the market;

h. Contracting with one or more PBMs and paying them rebates and other fees as consideration for their agreement to make Copaxone the exclusive or preferred version of glatiramer acetate that would be included on the PBMs' formularies, thus manipulating the choices available to patients and doctors and inducing payors to pay excessive amounts for Copaxone instead of paying for lower-cost generics;

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i. Contracting with certain specialty pharmacies and, on information and belief, providing certain specialty pharmacies with consideration in exchange for their agreement to fill generic glatiramer acetate prescriptions with Copaxone, circumventing the will of patients, the intent of doctors, and the design of health plans that favored generics over brand drugs;

j. Sending misleading messaging to patients and doctors regarding the need for doctors to write Copaxone prescriptions with the notation "Dispense as Written," including by informing patients that their out-of-pocket expenses (after using Teva's coupons) might be as low as $10 per month, in contravention of the requirements of the participants' health plans;

k. Concealing from the public Teva's deceptive practices which led to and permitted its Copaxone price increases and its inducement of payments from payors;

l. Misrepresenting and/or concealing from the public the true nature of the relationships between Defendants and ACS, AssistRx, TAF, CDF, PBMs, specialty pharmacies, and doctors and the effect of those relationships on the pricing of Copaxone; and

m. Failing to disclose and/or concealing from the public the true purpose of Teva's Copaxone-related patents, patent lawsuits, and citizens' petitions described herein.

327. Plaintiffs and the New York Members of the CPA Subclass were damaged and injured by Defendants' deceptive practices in violation of the New York GBL.

328. Defendants knew or should have known that their conduct was in violation of the New York GBL. Defendants' conduct was intentional and Defendants' violations were knowing and/or willful.

329. Plaintiffs and the New York Members of the CPA Subclass were damaged and injured by Defendants' illegal Medicare kickback scheme, which allowed Defendants to maintain their market share while charging artificially high prices for Copaxone for all payors, including private payors like Plaintiffs.

330. Teva's deceptive acts or practices, omissions, and misrepresentations were material to Plaintiffs and the Subclass, and were likely to and/or did deceive Plaintiffs and the Subclass, as well as patients and doctors, and further manipulated the prescribing and purchasing

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decisions of doctors and patients in order to unfairly induce Plaintiffs and the Subclass to pay for Copaxone at an inflated price instead of paying for lower-cost generics.

331. Plaintiffs and the Subclass, as well as the members of the private health plans for which Plaintiffs and the Subclass pay claims, relied upon Teva's material misrepresentations and omissions regarding Copaxone, as set forth above. These material misrepresentations and other deceptive practices by Defendants proximately caused Plaintiffs and the Subclass to pay for Copaxone instead of lower-cost generics and to overpay for Copaxone.

332. Plaintiffs and the Subclass suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Teva's deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for Copaxone and the difference between the prices paid for Copaxone and the prices they would have paid for lower-cost generics. Teva's violations also present a continuing risk to Plaintiffs and other payors in New York, who provide health coverage for thousands of patients afflicted by MS. Teva's violations further present a continuing risk to the general public, who in many cases are unable to afford or gain access to affordable treatment for MS. As such, Teva's unlawful acts and practices complained of herein affect the public interest.

333. Plaintiffs and the Subclass seek all remedies available under the New York GBL, including an order enjoining Teva's unfair and/or deceptive acts and practices, damages, treble and punitive damages as allowed, and attorneys' fees, costs, and any other just and proper relief available under the New York GBL. Because Teva's violations were knowing and/or willful, including its scheme to defraud Medicare in order to maintain market share while charging inflated prices for Copaxone, Plaintiffs' damages should be trebled to the extent permitted under the New York GBL. Because Teva's scheme involves a high degree of moral turpitude, an award of punitive damages is appropriate.

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D. Massachusetts

334. Plaintiffs and the Massachusetts Members of the CPA Subclass are "persons" within the meaning of Mass. Gen. Laws ch. 93A, § 11.

335. The Massachusetts Consumer Protection Act makes unlawful "[u]nfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce." Mass. Gen. Laws ch. 93A, §2.

336. Defendants engaged in unfair and deceptive acts and practices in violation of the Massachusetts Consumer Protection Act in an elaborate, multi-faceted scheme to increase the sales of Copaxone, inflate the price of Copaxone, manipulate the prescribing and purchasing decisions of doctors and patients, and induce Plaintiffs and the Subclass to pay for Copaxone at an inflated price instead of paying for lower-cost generics.

337. As set forth in more detail above in the factual allegations, examples of Teva's unfair and deceptive acts and practices that violate the Massachusetts Consumer Protection Act include, but are not limited to:

a. Defrauding Medicare by illegally funneling kickback payments to Medicare recipients through non-profits in order to induce False Claims against Medicare, thus isolating Teva from the price checks that would have been imposed by cost-sharing obligations and allowing Teva to increase and maintain the high list price of Copaxone for all sales, including to members of private health plans;

b. Causing ACS to certify false claims and PDEs with respect to Medicare claims induced by illegal kickbacks;

c. Using copay coupons to unfairly influence the purchasing decisions of private health plan members and induce private health plan payors, including Plaintiffs and the Subclass, to pay excessive amounts for Copaxone instead of paying for lower-cost generics;

d. Introducing a sham reformulation of Copaxone for the purpose of side-stepping drug substitution laws, thus inducing health plan payors to continue paying for high priced Copaxone instead of lower-cost generic forms of glatiramer acetate;

e. Misrepresenting the reasons for the introduction of 40mg Copaxone and engaging in an extensive outreach campaign through Teva's sales force to

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mislead patients and doctors so they would transition from 20mg Copaxone to 40mg Copaxone;

f. Concealing that: the product hop was part of a "generic defense strategy" to "minimize[e] generic substitution"; that Teva knew the change in dosage "does not represent a significant improvement in convenience"; that there was "no supporting data for the selected dose or dosing regimen"; that Teva's data "do not support going to higher doses"; that Teva's own scientists opposed testing the new dosage because it had "no scientific rationale / value"; and that Teva was in search for a pretextual justification for changing dosages;

g. Contracting with one or more PBMs who committed to relay these misrepresentations to physicians to get them to convert patients from 20mg to 40mg Copaxone before the generic 20mg generics hit the market;

h. Contracting with one or more PBMs and paying them rebates and other fees as consideration for their agreement to make Copaxone the exclusive or preferred version of glatiramer acetate that would be included on the PBMs' formularies, thus manipulating the choices available to patients and doctors and inducing payors to pay excessive amounts for Copaxone instead of paying for lower-cost generics;

i. Contracting with certain specialty pharmacies and, on information and belief, providing certain specialty pharmacies with consideration in exchange for their agreement to fill generic glatiramer acetate prescriptions with Copaxone, circumventing the will of patients, the intent of doctors, and the design of health plans that favored generics over brand drugs;

j. Sending misleading messaging to patients and doctors regarding the need for doctors to write Copaxone prescriptions with the notation "Dispense as Written," including by informing patients that their out-of-pocket expenses (after using Teva's coupons) might be as low as $10 per month, in contravention of the requirements of the participants' health plans;

k. Concealing from the public Teva's unfair and deceptive practices which led to and permitted its Copaxone price increases and its inducement of payments from payors;

l. Misrepresenting and/or concealing from the public the true nature of the relationships between Defendants and ACS, AssistRx, TAF, CDF, PBMs, specialty pharmacies, and doctors and the effect of those relationships on the pricing of Copaxone; and

m. Failing to disclose and/or concealing from the public the true purpose of Teva's Copaxone-related patents, patent lawsuits, and citizens' petitions described herein.

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338. Plaintiffs and the Massachusetts Members of the CPA Subclass were damaged and injured by Defendants' false and/or fraudulent misrepresentations and by Defendants conduct in violation of Mass. Gen. Laws ch. 93A, §11.

339. Plaintiffs were damaged and injured by Defendants' illegal Medicare kickback scheme, which allowed Defendants to maintain their market share while charging artificially high prices for Copaxone for all payors, including private payors like Plaintiffs.

340. Teva's unfair and deceptive acts or practices, omissions, and misrepresentations were material to Plaintiffs and the Subclass, and were likely to and/or did deceive Plaintiffs and the Subclass, as well as patients and doctors, and further manipulated the prescribing and purchasing decisions of doctors and patients in order to unfairly induce Plaintiffs and the Subclass to pay for Copaxone at an inflated price instead of paying for lower-cost generics.

341. Plaintiffs and the Subclass, as well as the members of the private health plans for which Plaintiffs and the Subclass pay claims, relied upon Teva's material misrepresentations and omissions regarding Copaxone, as set forth above. These material misrepresentations and other unfair and deceptive practices by Defendants proximately caused Plaintiffs and the Subclass to pay for Copaxone instead of lower-cost generics and to overpay for Copaxone.

342. Plaintiffs and the Subclass suffered substantial injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Teva's unfair and deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for Copaxone and the difference between the prices paid for Copaxone and the prices they would have paid for lower-cost generics. Teva's violations also present a continuing risk to Plaintiffs and other payors in Massachusetts, who provide health coverage for thousands of patients afflicted by MS. Teva's violations further present a continuing risk to the general public, who in many cases are unable to afford or gain access to affordable treatment for MS. As such, Teva's unlawful acts and practices complained of herein affect the public interest.

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343. Plaintiffs and the Subclass seek an order enjoining Teva's unfair and/or deceptive acts or practices, damages, punitive damages, and attorneys' fees, costs, and any other just and proper relief available under the Massachusetts Consumer Protection Act.

E. California

344. Plaintiffs and the California Members of the CPA Subclass are "persons" within the meaning of the California Unfair Competition Law ("UCL"). Cal. Bus. & Prof. Code § 17201.

345. The UCL prohibits "any unlawful, unfair or fraudulent business act or practice." *Id.* § 17200.

346. Defendants engaged in unlawful, unfair or fraudulent business acts and practices in violation of the UCL in an elaborate, multi-faceted scheme to increase the sales of Copaxone, inflate the price of Copaxone, manipulate the prescribing and purchasing decisions of doctors and patients, and induce Plaintiffs and the Subclass to pay for Copaxone at an inflated price instead of paying for lower-cost generics.

347. As set forth in more detail above in the factual allegations, examples of Teva's deceptive acts and practices that violate the UCL include but are not limited to:

a. Defrauding Medicare by illegally funneling kickback payments to Medicare recipients through non-profits in order to induce False Claims against Medicare, thus isolating Teva from the price checks that would have been imposed by cost-sharing obligations and allowing Teva to increase and maintain the high list price of Copaxone for all sales, including to members of private health plans;

b. Causing ACS to certify false claims and PDEs with respect to Medicare claims induced by illegal kickbacks;

c. Using copay coupons to unfairly influence the purchasing decisions of private health plan members and induce private health plan payors, including Plaintiffs and the Subclass, to pay excessive amounts for Copaxone instead of paying for lower-cost generics;

d. Introducing a sham reformulation of Copaxone for the purpose of side-stepping drug substitution laws, thus inducing health plan payors to continue paying for high priced Copaxone instead of lower-cost generic forms of glatiramer acetate;

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e. Misrepresenting the reasons for the introduction of 40mg Copaxone and engaging in an extensive outreach campaign through Teva's sales force to mislead patients and doctors so they would transition from 20mg Copaxone to 40mg Copaxone;

f. Concealing that: the product hop was part of a "generic defense strategy" to "minimize[e] generic substitution"; that Teva knew the change in dosage "does not represent a significant improvement in convenience"; that there was "no supporting data for the selected dose or dosing regimen"; that Teva's data "do not support going to higher doses"; that Teva's own scientists opposed testing the new dosage because it had "no scientific rationale / value"; and that Teva was in search for a pretextual justification for changing dosages;

g. Contracting with one or more PBMs who committed to relay these misrepresentations to physicians to get them to convert patients from 20mg to 40mg Copaxone before the generic 20mg generics hit the market;

h. Contracting with one or more PBMs and paying them rebates and other fees as consideration for their agreement to make Copaxone the exclusive or preferred version of glatiramer acetate that would be included on the PBMs' formularies, thus manipulating the choices available to patients and doctors and inducing payors to pay excessive amounts for Copaxone instead of paying for lower-cost generics;

i. Contracting with certain specialty pharmacies and, on information and belief, providing certain specialty pharmacies with consideration in exchange for their agreement to fill generic glatiramer acetate prescriptions with Copaxone, circumventing the will of patients, the intent of doctors, and the design of health plans that favored generics over brand drugs;

j. Sending misleading messaging to patients and doctors regarding the need for doctors to write Copaxone prescriptions with the notation "Dispense as Written," including by informing patients that their out-of-pocket expenses (after using Teva's coupons) might be as low as $10 per month, in contravention of the requirements of the participants' health plans;

k. Concealing from the public Teva's deceptive practices which led to and permitted its Copaxone price increases and its inducement of payments from payors;

l. Misrepresenting and/or concealing from the public the true nature of the relationships between Defendants and ACS, AssistRx, TAF, CDF, PBMs, specialty pharmacies, and doctors and the effect of those relationships on the pricing of Copaxone; and

m. Failing to disclose and/or concealing from the public the true purpose of Teva's Copaxone-related patents, patent lawsuits, and citizens' petitions described herein.

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348. Defendants' UCL violations were the proximate cause of injuries to the Plaintiffs and the California Members of the CPA Subclass.

349. Defendants knew or should have known that their conduct was in violation of the UCL. Defendants' conduct was intentional and Defendants' violations were knowing and/or willful.

350. Plaintiffs and the Subclass were injured by Defendants' illegal Medicare kickback scheme, which allowed Defendants to maintain their market share while charging artificially high prices for Copaxone for all payors, including private payors like Plaintiffs.

351. Defendants' deceptive acts or practices, omissions, and misrepresentations were material to Plaintiffs and the Subclass, and were likely to and/or did deceive Plaintiffs and the Subclass, as well as patients and doctors, and further manipulated the prescribing and purchasing decisions of doctors and patients in order to unfairly induce Plaintiffs and the Subclass to pay for Copaxone at an inflated price instead of paying for lower-cost generics.

352. Plaintiffs and the Subclass, as well as the members of the private health plans for which Plaintiffs and the Subclass pay claims, relied upon Teva's material misrepresentations and omissions regarding Copaxone, as set forth above. These material misrepresentations and other deceptive practices by Defendants proximately caused Plaintiffs and the Subclass to pay for Copaxone instead of lower-cost generics and to overpay for Copaxone.

353. Plaintiffs and the Subclass suffered injury-in-fact and ascertainable loss as a direct and proximate result of Teva's deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for Copaxone and the difference between the prices paid for Copaxone and the prices they would have paid for lower-cost generics. Teva's violations also present a continuing risk to Plaintiffs and other payors in California, who provide health coverage for thousands of patients afflicted by MS. Teva's violations further present a continuing risk to the general public, who in many cases are unable to

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afford or gain access to affordable treatment for MS. As such, Teva's unlawful acts and practices complained of herein affect the public interest.

354. Plaintiffs and the Subclass seek all remedies available under the UCL, including an order enjoining Teva's unfair and/or deceptive acts and practices, full restitution and disgorgement of all profits, revenues, and other benefits Teva obtained as a result of the acts and practices alleged herein, and attorneys' fees, costs, and any other just and proper relief available under the UCL.

F. Florida

355. Plaintiffs and the Florida Members of the CPA Subclass are "consumers" within the meaning of the Florida Deceptive and Unfair Trade Practices Act (the "Florida Act"). Fl. Stat. Ann. § 501.203(7).

356. Plaintiffs and the Florida Members of the CPA Subclass are "persons" within the meaning of the Florida Act's provision authorizing actions for damages "by a person who has suffered a loss as a result of a violation" of the Florida Act. Fl. Stat. Ann. § 501.211(2).

357. Defendants are engaged in "trade or commerce" within the meaning of the Florida Act. *Id.* § 501.203(8).

358. The Florida Act prohibits "[u]nfair methods of competition, unconscionable acts or practices, and unfair or deceptive acts or practices in the conduct of any trade or commerce." *Id.* § 501.204(1).

359. Defendants engaged in unfair or deceptive acts and practices in violation of the Florida Act in an elaborate, multi-faceted scheme to increase the sales of Copaxone, inflate the price of Copaxone, manipulate the prescribing and purchasing decisions of doctors and patients, and induce Plaintiffs and the Subclass to pay for Copaxone at an inflated price instead of paying for lower-cost generics.

360. As set forth in more detail above in the factual allegations, examples of Teva's deceptive acts and practices that violate the Florida Act include but are not limited to:

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a. Defrauding Medicare by illegally funneling kickback payments to Medicare recipients through non-profits in order to induce False Claims against Medicare, thus isolating Teva from the price checks that would have been imposed by cost-sharing obligations and allowing Teva to increase and maintain the high list price of Copaxone for all sales, including to members of private health plans;

b. Causing ACS to certify false claims and PDEs with respect to Medicare claims induced by illegal kickbacks;

c. Using copay coupons to unfairly influence the purchasing decisions of private health plan members and induce private health plan payors, including Plaintiffs and the Subclass, to pay excessive amounts for Copaxone instead of paying for lower-cost generics;

d. Introducing a sham reformulation of Copaxone for the purpose of side-stepping drug substitution laws, thus inducing health plan payors to continue paying for high priced Copaxone instead of lower-cost generic forms of glatiramer acetate;

e. Misrepresenting the reasons for the introduction of 40mg Copaxone and engaging in an extensive outreach campaign through Teva's sales force to mislead patients and doctors so they would transition from 20mg Copaxone to 40mg Copaxone;

f. Concealing that: the product hop was part of a "generic defense strategy" to "minimize[e] generic substitution"; that Teva knew the change in dosage "does not represent a significant improvement in convenience"; that there was "no supporting data for the selected dose or dosing regimen"; that Teva's data "do not support going to higher doses"; that Teva's own scientists opposed testing the new dosage because it had "no scientific rationale / value"; and that Teva was in search for a pretextual justification for changing dosages;

g. Contracting with one or more PBMs who committed to relay these misrepresentations to physicians to get them to convert patients from 20mg to 40mg Copaxone before the generic 20mg generics hit the market;

h. Contracting with one or more PBMs and paying them rebates and other fees as consideration for their agreement to make Copaxone the exclusive or preferred version of glatiramer acetate that would be included on the PBMs' formularies, thus manipulating the choices available to patients and doctors and inducing payors to pay excessive amounts for Copaxone instead of paying for lower-cost generics;

i. Contracting with certain specialty pharmacies and, on information and belief, providing certain specialty pharmacies with consideration in exchange for their agreement to fill generic glatiramer acetate prescriptions with Copaxone, circumventing the will of patients, the intent of doctors, and the design of health plans that favored generics over brand drugs;

j. Sending misleading messaging to patients and doctors regarding the need for doctors to write Copaxone prescriptions with the notation "Dispense as Written," including by informing patients that their out-of-pocket expenses

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(after using Teva's coupons) might be as low as $10 per month, in contravention of the requirements of the participants' health plans;

k. Concealing from the public Teva's deceptive practices which led to and permitted its Copaxone price increases and its inducement of payments from payors;

l. Misrepresenting and/or concealing from the public the true nature of the relationships between Defendants and Advanced Care, AssistRx, The Assistance Fund, Chronic Disease Fund, PBMs, specialty pharmacies, and doctors and the effect of those relationships on the pricing of Copaxone; and

m. Failing to disclose and/or concealing from the public the true purpose of Teva's Copaxone-related patents, patent lawsuits, and citizens' petitions described herein.

361. Plaintiffs and the Florida Members of the CPA Subclass were damaged and injured by defendants' deceptive practices in violation of the Florida Act.

362. Defendants knew or should have known that their conduct was in violation of the Florida Act. Defendants' conduct was intentional and Defendants' violations were knowing and/or willful.

363. Plaintiffs and the Subclass were damaged and injured by Defendants' illegal Medicare kickback scheme, which allowed Defendants to maintain their market share while charging artificially high prices for Copaxone for all payors, including private payors like Plaintiffs.

364. Defendants' deceptive acts or practices, omissions, and misrepresentations were material to Plaintiffs and the Subclass, and were likely to and/or did deceive Plaintiffs and the Subclass, as well as patients and doctors, and further manipulated the prescribing and purchasing decisions of doctors and patients in order to unfairly induce Plaintiffs and the Subclass to pay for Copaxone at an inflated price instead of paying for lower-cost generics.

365. Plaintiffs and the Subclass, as well as the members of the private health plans for which Plaintiffs and the Subclass pay claims, relied upon Teva's material misrepresentations and omissions regarding Copaxone, as set forth above. These material misrepresentations and other

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deceptive practices by Defendants proximately caused Plaintiffs and the Subclass to pay for Copaxone instead of lower-cost generics and to overpay for Copaxone.

366. Plaintiffs and the Subclass suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Teva's deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for Copaxone and the difference between the prices paid for Copaxone and the prices they would have paid for lower-cost generics. Teva's violations also present a continuing risk to Plaintiffs and other payors in Florida, who provide health coverage for thousands of patients afflicted by MS. Teva's violations further present a continuing risk to the general public, who in many cases are unable to afford or gain access to affordable treatment for MS. As such, Teva's unlawful acts and practices complained of herein affect the public interest.

367. Plaintiffs and the Subclass seek all remedies available under the Florida Act, including an order enjoining Teva's unfair and/or deceptive acts and practices, and damages as allowed, and attorneys' fees, costs, and any other just and proper relief available under the Florida Act.

G. Delaware

368. Plaintiffs and the Delaware Members of the CPA Subclass are "victims" within the meaning of the Delaware Consumer Fraud Act, Del. Code Ann. tit. 6, § 2525.

369. Defendants are engaged in the sale and advertisement of merchandise within the meaning of the Delaware Consumer Fraud Act. Del. Code Ann. tit. 6, § 2513.

370. The Delaware Consumer Fraud Act makes unlawful the "act, use, or employment by any person of any deception, fraud, false pretense, false promise, misrepresentation, unfair practice, or the concealment, suppression, or omission of any material fact with intent that others rely upon such concealment, suppression, or omission, in connection with the sale, lease, receipt, or advertisement of any merchandise." Del. Code Ann. tit. 6, § 2513.

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371. Defendants engaged in unfair or deceptive acts and practices in violation of the Delaware Consumer Fraud Act in an elaborate, multi-faceted scheme to increase the sales of Copaxone, inflate the price of Copaxone, manipulate the prescribing and purchasing decisions of doctors and patients, and induce Plaintiffs and the Subclass to pay for Copaxone at an inflated price instead of paying for lower-cost generics.

372. As set forth in more detail above in the factual allegations, examples of Teva's deceptive acts and practices that violate the Delaware Consumer Fraud Act include but are not limited to:

a. Defrauding Medicare by illegally funneling kickback payments to Medicare recipients through non-profits in order to induce False Claims against Medicare, thus isolating Teva from the price checks that would have been imposed by cost-sharing obligations and allowing Teva to increase and maintain the high list price of Copaxone for all sales, including to members of private health plans;

b. Causing ACS to certify false claims and PDEs with respect to Medicare claims induced by illegal kickbacks;

c. Using copay coupons to unfairly influence the purchasing decisions of private health plan members and induce private health plan payors, including Plaintiffs and the Subclass, to pay excessive amounts for Copaxone instead of paying for lower-cost generics;

d. Introducing a sham reformulation of Copaxone for the purpose of side-stepping drug substitution laws, thus inducing health plan payors to continue paying for high priced Copaxone instead of lower-cost generic forms of glatiramer acetate;

e. Misrepresenting the reasons for the introduction of 40mg Copaxone and engaging in an extensive outreach campaign through Teva's sales force to mislead patients and doctors so they would transition from 20mg Copaxone to 40mg Copaxone;

f. Concealing that: the product hop was part of a "generic defense strategy" to "minimize[e] generic substitution"; that Teva knew the change in dosage "does not represent a significant improvement in convenience"; that there was "no supporting data for the selected dose or dosing regimen"; that Teva's data "do not support going to higher doses"; that Teva's own scientists opposed testing the new dosage because it had "no scientific rationale / value"; and that Teva was in search for a pretextual justification for changing dosages;

g. Contracting with one or more PBMs who committed to relay these misrepresentations to physicians to get them to convert patients from 20mg to 40mg Copaxone before the generic 20mg generics hit the market;

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h. Contracting with one or more PBMs and paying them rebates and other fees as consideration for their agreement to make Copaxone the exclusive or preferred version of glatiramer acetate that would be included on the PBMs' formularies, thus manipulating the choices available to patients and doctors and inducing payors to pay excessive amounts for Copaxone instead of paying for lower-cost generics;

i. Contracting with certain specialty pharmacies and, on information and belief, providing certain specialty pharmacies with consideration in exchange for their agreement to fill generic glatiramer acetate prescriptions with Copaxone, circumventing the will of patients, the intent of doctors, and the design of health plans that favored generics over brand drugs;

j. Sending misleading messaging to patients and doctors regarding the need for doctors to write Copaxone prescriptions with the notation "Dispense as Written," including by informing patients that their out-of-pocket expenses (after using Teva's coupons) might be as low as $10 per month, in contravention of the requirements of the participants' health plans;

k. Concealing from the public Teva's deceptive practices which led to and permitted its Copaxone price increases and its inducement of payments from payors;

l. Misrepresenting and/or concealing from the public the true nature of the relationships between Defendants and ACS, AssistRx, TAF, CDF, PBMs, specialty pharmacies, and doctors and the effect of those relationships on the pricing of Copaxone; and

m. Failing to disclose and/or concealing from the public the true purpose of Teva's Copaxone-related patents, patent lawsuits, and citizens' petitions described herein.

373. Plaintiffs and the Delaware Members of the CPA Subclass were damaged and injured by defendants' deceptive practices in violation of the Delaware Consumer Fraud Act.

374. Defendants knew or should have known that their conduct was in violation of the Delaware Consumer Fraud Act. Defendants' conduct was intentional and Defendants' violations were knowing and/or willful. Defendants' fraud, including their illegal Medicare kickback scheme, was gross, oppressive, and/or aggravated, and warrants an award of punitive damages.

375. Plaintiffs and the Subclass were damaged and injured by Defendants' illegal Medicare kickback scheme, which allowed Defendants to maintain their market share while charging artificially high prices for Copaxone for all payors, including private payors like Plaintiffs.

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376. Defendants' deceptive acts or practices, omissions, and misrepresentations were material to Plaintiffs and the Subclass, and were likely to and/or did deceive Plaintiffs and the Subclass, as well as patients and doctors, and further manipulated the prescribing and purchasing decisions of doctors and patients in order to unfairly induce Plaintiffs and the Subclass to pay for Copaxone at an inflated price instead of paying for lower-cost generics.

377. Plaintiffs and the Subclass, as well as the members of the private health plans for which Plaintiffs and the Subclass pay claims, relied upon Teva's material misrepresentations and omissions regarding Copaxone, as set forth above. These material misrepresentations and other deceptive practices by Defendants proximately caused Plaintiffs and the Subclass to pay for Copaxone instead of lower-cost generics and to overpay for Copaxone.

378. Plaintiffs and the Subclass suffered injury-in-fact, ascertainable loss, and actual damages as a direct and proximate result of Teva's deceptive practices and omissions and/or misrepresentations, at a minimum, in the form of increased and unfair prices paid for Copaxone and the difference between the prices paid for Copaxone and the prices they would have paid for lower-cost generics. Teva's violations also present a continuing risk to Plaintiffs and other payors in Delaware, who provide health coverage for thousands of patients afflicted by MS. Teva's violations further present a continuing risk to the general public, who in many cases are unable to afford or gain access to affordable treatment for MS. As such, Teva's unlawful acts and practices complained of herein affect the public interest.

Plaintiffs and the Subclass seek all remedies available under the Delaware Consumer Fraud Act, including an order enjoining Teva's unfair and/or deceptive acts and practices, damages, and punitive damages as allowed, and attorneys' fees, costs, and any other just and proper relief available under the Delaware Consumer Fraud Act.

SIXTH COUNT — UNJUST ENRICHMENT
(on behalf of Plaintiffs and the Class)

379. Plaintiffs repeat and re-allege every allegation above as if set forth herein in full.

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380. Plaintiffs bring this claim on behalf of themselves and the Class under the common law of all U.S. states and territories.

381. By reason of their conduct, Defendants caused damages to Plaintiffs and to Members of the Class.

382. By purchasing the Copaxone at an inflated price, which Teva forced them to do, Plaintiffs and the Class Members conferred a benefit on Teva in the form of the inflated and unconscionable prices they paid for Copaxone.

383. Teva appreciated the benefit because, had consumers not purchased Copaxone, Teva would have no sales and derive no benefit from sales of Copaxone.

384. Teva was directly involved in setting the price, making material misstatements, and directing the sale and distribution of Copaxone nationwide in the United States.

385. Teva's acceptance and retention of the benefit is inequitable and unjust because the benefit was obtained by Teva's price gouging, unconscionable sales, and unlawful acts, as set forth above.

386. Equity cannot in good conscience permit Teva to be economically enriched for its unjust actions at Plaintiffs' and Class Members' expense and in violation of state law, and therefore restitution or disgorgement or both of such economic enrichment is required.

XII. PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. Determine that this action may be maintained as a class action pursuant to Fed. R. Civ. P. 23(a) and (b)(3) and direct that reasonable notice of this action, as provided by Fed. R. Civ. P. 23(c)(2) be given to the Class;

B. Require Teva to pay for sending notice to the certified Class;

C. Appoint Plaintiffs as Class Representatives and Plaintiffs' counsel as Class Counsel;

D. Issue an injunction to enjoin Teva from engaging in the anticompetitive, deceptive, unfair, unconscionable, and unlawful business practices alleged in this Complaint;

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E. Award further injunctive relief, as the Court deems appropriate;

F. Award compensatory damages to Plaintiffs and the proposed Class in an amount to be established at trial, or, alternatively, require Defendant to disgorge or pay restitution in an amount to be determined at trial;

G. Award treble damages as permitted by law;

H. Award pre- and post-judgment interest;

I. Award punitive damages based on Teva's reprehensible and deliberate conduct;

J. Award reasonable attorneys' fees and costs; and,

K. Award all such other and further relief as may be just and proper.

XIII. DEMAND FOR JURY TRIAL

Plaintiffs hereby demand a jury trial for all claims so triable.

DATED: August 22, 2022.

Respectfully submitted,

STRIS & MAHER LLP

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Bridget C. Asay

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